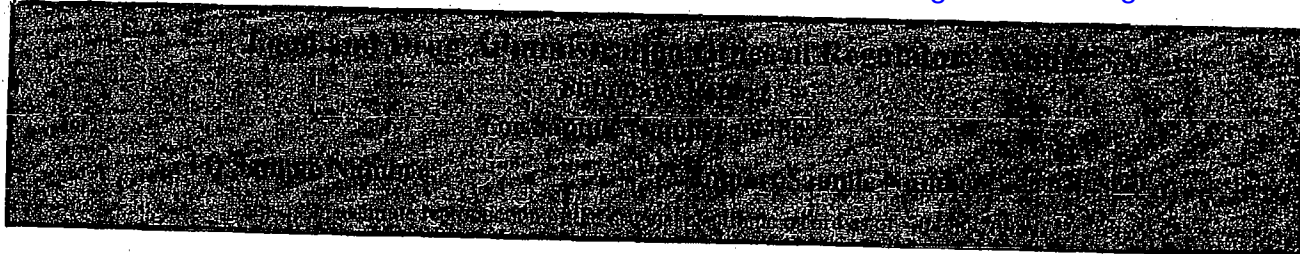


EXHIBIT 34



Sample Class: Normal Everyday Sample
Survey Sample

Sample Origin: Domestic

Sample Basis: Surveillance

Sample Type: Official

Collecting District: DET-DO

Home District:

Orig C/R and Records To: DAL-DO

Collection PACs: 56008A

Product Name: Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Prompt Release Tablets

Product Description: 100 x 0.25mg Digoxin Tablets, USP

Collection Reason: The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

Lab: NRL	Split Num 0	Date Received: 12/18/2007	Date Out of Lab: 04/29/2008
District Conclusion:		District Conclusion Made By:	District
Disposition Reason:		Disposition Authorized By:	Disposition Authorized Date

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NRL-DCB-G	56008A		DRT		1 - In Compliance	Completed

Lab Conclusion

The product meets specifications for Identification, Dissolution and Content Uniformity.

Lab Conclusion Date

Lab Conclusion Made By

04/29/2008

Mathew, Samuel K

Date: 04/30/2008

Page: 1 of 1



Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 448892**

This is an accurate reproduction of the original electronic record as of 12/14/2007

Flag		Flag Remarks			
Survey Sample		FY 2008 Low Cost Generic Drug Sample Survey # 2008-800			
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	0882662	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1610608	12/03/2007	63FCA06	Shipper	56008A	2
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	DET-DO	62794-146-01		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Digitex	

Product Description

100 x 0.25mg Digoxin Tablets, USP

Product Label

See continuation.

Reason for Collection

The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

MFG Codes

70664A1

Expiration Date

Aug 2009

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
UDL Laboratories, Inc	12720 Dairy Ashford Rd Sugar Land, TX 77478-2844 US	Shipper	1610608	
Actavis Totowa LLC *	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	2244683	
Wal-Mart Pharmacy Warehouse #6028	801 Corda Blvd Crawfordsville, IN 47933-2152 US	Dealer	3004344335	
Size of Lot	Est. Value	Rept Type	Carrier Name	Date Shipped
(b) (4) x 100 count bottles		FDA484		

Description of Sample

The sample consists of 2 x 100 count 0.25mg Digitex (Digoxin Tablets, USP) with NDC # 62794-146-01 and assigned lot # 706641A and expiry date 8/2009.

Method of Collection

2 x 100 count bottles of 0.25mg Digitex (Digoxin Tablets, USP) lot 70664A1 were randomly selected from shelf.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"Sample # 448892 EB 12/3/07"

Collector's Identification on Seal

"448892 Ernest Bizjak 12/3/07"

Sample Delivered To

FEDEX

Date Delivered

12/17/2007

Orig C/R & Records To

DAL-DO

Lab w/Split Sample

0

Lab

NRL

Date: 12/14/2007

Page: 1 of 3

**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 448892

This is an accurate reproduction of the original electronic record as of 12/14/2007

Document Number	Document Date	Document Type	Document Remarks
	12/03/2007	Other	FDA-482; 1 page
	12/03/2007	Other	FDA-484; 4 pages

Remarks
See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
	No Charge	No	No	Ernest Bizjak

Name of Signer	Date & Time of Signature	Meaning
Ernest Bizjak	12/14/2007 09:15 AM ET	Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 448892

This is an accurate reproduction of the original electronic record as of 12/14/2007

Continuation:

Product Label

The white HDPE bottle with matching screw cap is labeled in part "NDC 62794-146-01 *** DIGITEK (digoxin tablets, USP) *** 250mcg (0.25 mg) *** 100 TABLETS *** Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 *** Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA *** Control No.: 70664A1 *** Exp. Date: Aug 09".

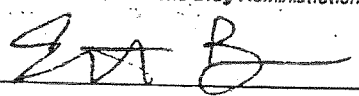
How Prepared

The 2 bottles were identified as per Collector's ID and placed into a clear Whirl-pak bag that was then officially sealed at the dealer. The sample was transported back to the DET-DO/INDY-RP where it was stored in a locked sample cabinet at ambient conditions until it was boxed and shipped to lab.

Remarks

Per assignment memo, test sample for UDU, Diss, and ID. All analytical methods are compendial.

Dena McClamroch, General Manager stated that she could not provide a dollar value for the sample. If this information is needed, contact Monty Mason, Pharmacy Director at ph#479-277-1558.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. DISTRICT OFFICE ADDRESS & PHONE NO. DET. DIV # 312-342-8100 300 Ann Arbor, Suite 5900 Detroit MI 48207	
2. NAME AND TITLE OF INDIVIDUAL Dana M. McCamroch		3. DATE 12/3/07	
4. FIRM NAME Wal-Mart		5. HOUR 9:25 a.m.	
6. NUMBER AND STREET 801 Cor-dea Blvd.		7. CITY AND STATE & ZIP CODE Crawfordsville, IN 47933	
8. PHONE # & AREA CODE 765/361-4192			
Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)]¹ and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264]²			
9. SIGNATURE (Food and Drug Administration Employee(s)) 		10. TYPE OR PRINT NAME AND TITLE (FDA Employee(s)) Ernest Bizjak, Investigator	
<p>¹ Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:</p> <p>Sec. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs and devices and, subject to reporting and inspection under regulations lawfully issued pursuant to section 505(l) or (k), section 507(d) or (g), section 519, or 520(g)), and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.</p> <p>Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.</p> <p>Section 704 (f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.</p> <p>Section 512 (1)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by</p>		<p>order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.</p> <p>(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.</p> <p>² Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:</p> <p>Part F - Licensing - Biological Products and Clinical Laboratories and*****</p> <p>Sec. 351(c) "Any officer, agent, or employee of the Department of Health & Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."</p> <p>Part F - *****Control of Radiation.</p> <p>Sec. 360 A(a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests for testing programs required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."</p> <p>(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."</p> <p style="text-align: center;">*****</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER

DET-DO # 313-393-8100
300 River Place, Suite 5900
Detroit, MI 48207

2. NAME AND TITLE OF INDIVIDUAL

Dena M. McClamroch, General Manager

3. DATE

12/3/07

4. SAMPLE NUMBER

*See below *

5. FIRM NAME

Wal-Mart

6. FIRM'S DEA NUMBER

7. NUMBER AND STREET

801 Cor - du Blvd

8. CITY AND STATE (Include Zip Code)

Crawfordsville, IN 47933

9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360i(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.

(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

Sample #414930 consists of

① 2 x 100 bottles Captopril Tablets, 12.5mg, lot DG10952 with NDC # 64671-902-01

② Sample #414931 consists of 53 x 3.5g tubes Erythromycin Ophthalmic Ointment, 5mg/g, lot P53 with NDC # 0168-0070-38

③ Sample #414932 consists of 2 x 100 bottles Hydrochlorothiazide Capsules, 12.5mg, lot 350713 with NDC # 0378-0810-01

④ Sample #414933 consists of 2 x 100 bottles Estrocel Tablets, 0.5mg, lot 304344 with NDC # 0555-0899-02

⑤ Sample #414934 consists of 2 x 100 bottles Atenolol Tablets, 25mg, lot 151437 with NDC # 0378-0218-01

⑥ Sample #414935 consists of 1 x 500 bottle Amoxicillin Capsules, 250mg, lot # 022011 with NDC # 0781-2020-05

⑦ Sample #414936 consists of 2 x 100 bottles Endopril Maleate Tablets, 2.5mg, lot # 27875 with NDC # 0093-0026-01

⑧ Sample #414937 consists of 22 bottles Amoxicillin for Oral Suspension, 200mg/5ml, lot # 1755794, NDC # 63304-469-03

10. SAMPLES WERE

- ☒ PROVIDED AT NO CHARGE
☐ PURCHASED
☐ BORROWED (To be returned)

11. AMOUNT RECEIVED FOR SAMPLE

- ☒ No Charge ☐ CASH ☐ BILLED
☐ VOUCHER ☐ CREDIT CARD

12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)

Dena McClamroch

13. COLLECTOR'S NAME (Print or Type)

Ernest B. Jank

14. COLLECTOR'S TITLE (Print or Type)

Inspector

15. COLLECTOR'S SIGNATURE

EJB

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

1. DISTRICT ADDRESS & PHONE NUMBER
DET. DO #313-393-8100
300 River Place, Suite 5900
Detroit, MI 48207

2. NAME AND TITLE OF INDIVIDUAL

Dana M. McClanroch General Manager

3. DATE

12/3/07

4. SAMPLE NUMBER

See below

5. FIRM NAME

Wad-Mat

6. FIRM'S DEA NUMBER

7. NUMBER AND STREET

801 Cor-da Blvd.

8. CITY AND STATE (Include Zip Code)

Crawfordsville, IN 47933

9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification)

The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(c)) and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act (21 USC 360i(b)) and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.

(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)

(9) Clonidine EB 12/3/07

(9) Sample #448877 consists of 3x90 boxes Clonidine HCl Tablets, 0.1mg, lot 711833, NDC # 51079-299-62

(10) Sample #448878 consists of 2x100 bottles Bisoprolol Fumarate / Hydrochlorothiazide Tablets, 2.5 / 6.25mg, lot 150806 with NDC # 0378-0501-01

(11) Sample #448879 consists of 53x15g tubes Gentamicin Sulfate Ointment, 0.1%, lot Z176 with NDC # 0168-0078-15

(12) Sample #448880 consists of 2x100 bottles Glyburide Tablets, 2.5mg, lot 149347A with NDC # 0093-8343-61

(13) Sample #448881 consists of 2x100 bottles Digitek (Digoxin) Tablets, 0.125mg, lot 70298A1 with NDC # 62794-145-01

(14) Sample #448882 consists of 7x30 bottles Citalopram HBr Tablets, 20mg, lot C72275 with NDC # 55111-343-30

(15) Sample #448883 consists of 83x5mL bottles Gentamicin Sulfate Ophthalmic Solution, 3mg/mL, lot 729553F with NDC # 61314-633-05

(16) Sample #448884 consists of 2x100 bottles Ciprofloxacin Tablets, 250mg, lot # 1717002 with NDC # 63304-709-01
EB 12/3/07

10. SAMPLES WERE

- ☒ PROVIDED AT NO CHARGE
☐ PURCHASED
☐ BORROWED (To be returned)

11. AMOUNT RECEIVED FOR SAMPLE

- ☒ No ☐ CASH ☐ BILLED
☐ VOUCHER ☐ CREDIT CARD

12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.)

Dana McClanroch

13. COLLECTOR'S NAME (Print or Type)


Ernest Bizjak

14. COLLECTOR'S TITLE (Print or Type)

Investigator

15. COLLECTOR'S SIGNATURE

EB

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER DET. DO # 313-393-8100 300 River Place, S.W. 5th Fl. Detroit, MI 48207	
2. NAME AND TITLE OF INDIVIDUAL Dana M. McClamrock, General Manager		3. DATE 12/3/07	4. SAMPLE NUMBER *see below
5. FIRM NAME WHL-Mart		6. FIRM'S DEA NUMBER 	
7. NUMBER AND STREET 801 Cor-dee Blvd.		8. CITY AND STATE (Include Zip Code) Crawfordsville, IN 47933	
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) <p>The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360ii(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.</p> <p>(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)</p> <p>(17) Sample # 448885 consists of 2x100 bottles Erythrocine Tablets, 250 mg, lot 56753AF22 with NDC # 0074-6346-20</p> <p>(18) Sample # 448886 consists of 2x100 bottles Acyclovir Capsules, 700 mg, lot 35300555A with NDC # 0093-8940-01</p> <p>(19) Sample # 448887 consists of 2x100 bottles Bumetanide Tablets, 0.5 mg, lot 1V76033 with NDC # 0093-4232-01</p> <p>(20) Sample # 448888 consists of 2x100 bottles Dexamethasone Methylate Tablets, 1 mg, lot 3000793 with NDC # 0378-4021-01</p> <p>(21) Sample # 448889 consists of 2x100 bottles Famotidine Tablets, 20 mg, lot BEB02A with NDC # 0172-5728-60</p> <p>(22) Sample # 448890 consists of 53x3.5g tubes Bacitracin Ophthalmic Ointment, 500 U/g, lot P72 with NDC # 0168-0026-38</p> <p>(23) Sample # 448891 consists of 54x20mL bottles Albuterol Sulfate Inhalation Solution, 0.5%, lot 157641, with NDC # 24208-347-20</p> <p>(24) Sample # 448892 consists of 2x100 bottles Digitek (Digoxin) Tablets, 0.25 mg, lot 70664A1, with NDC # 62794-146-01</p>			
10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> No charge <input type="checkbox"/> CASH <input type="checkbox"/> BILLED <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD	
13. COLLECTOR'S NAME (Print or Type) Ernst Bizjak		12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) Dana M. McClamrock	
14. COLLECTOR'S TITLE (Print or Type) Investigator		15. COLLECTOR'S SIGNATURE 	

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		1. DISTRICT ADDRESS & PHONE NUMBER DET. DO #313-393-8100 300 River Place, Suite 5900 Detroit, MI 48207	
2. NAME AND TITLE OF INDIVIDUAL Dina M. McClamroch General Manager		3. DATE 12/3/07	4. SAMPLE NUMBER # see below *
5. FIRM NAME Wal-Mart	6. FIRM'S DEA NUMBER		
7. NUMBER AND STREET 801 Cor-dea Blvd.	8. CITY AND STATE (Include Zip Code) Crawfordsville, IN 47933		
9. SAMPLE COLLECTED (Describe fully. List lot, serial, model numbers and other positive identification) <p>The following samples were collected by the Food and Drug Administration and receipt is hereby acknowledged pursuant to Section 704(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(c)] and / or Section 532 (b) of the Federal Food, Drug, and Cosmetic Act [21 USC 360i(b)] and/or 21 Code of Federal Regulations (CFR) 1307.02. Excerpts of these are quoted on the reverse of this form.</p> <p>(NOTE: If you bill FDA for the cost of the Sample(s) listed below, please attach a copy of this form to your bill.)</p> <p>(25) Sample # 448893 consists of 2x100 bottles Diltiazem HCL Tablets, 30mg, lot 001047 with NDC # 0093-0318-01</p> <p>(26) Sample # 448894 consists of 1x1000 bottle Amitriptyline HCL Tablets, 10mg, lot 1P5678 with NDC # 0378-2610-10</p> <p>(27) Sample # 448895 consists of 2x100 bottles Epitol (Carbamazepine) Tablets, 200mg, lot 211870 with NDC # 0093-0090-01</p> <p>(28) Sample # 448896 consists of 2x100 bottles Fluoxetine Capsules, 10mg, lot 148748A with NDC # 0093-1042-01</p> <p style="font-size: 1.2em; margin-top: 20px;">These samples were provided free of charge.</p>			
10. SAMPLES WERE <input checked="" type="checkbox"/> PROVIDED AT NO CHARGE <input type="checkbox"/> PURCHASED <input type="checkbox"/> BORROWED (To be returned)		11. AMOUNT RECEIVED FOR SAMPLE <input checked="" type="checkbox"/> No Charge <input type="checkbox"/> CASH <input type="checkbox"/> BILLED <input type="checkbox"/> VOUCHER <input type="checkbox"/> CREDIT CARD	
12. SIGNATURE (Persons receiving payment for sample or person providing sample to FDA at no charge.) Dina M. McClamroch		13. COLLECTOR'S NAME (Print or Type) Ernest B. Zajac	
14. COLLECTOR'S TITLE (Print or Type) Investigator		15. COLLECTOR'S SIGNATURE E.B. Zajac	

FLAG Original

ANALYST WORKSHEET		1. PRODUCT DIGITEK (digoxin tablets, USP) 250 mcg (0.25 mg)		2. SAMPLE NUMBER 448892	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 2/4/08	5. RECEIVED FROM Howard Lynch		6. DISTRICT OF LABORATORY NRL
7. DESCRIPTION OF SAMPLE One clear, plastic bag officially sealed, "448892 12/3/07 Ernest Bizjak Investigator", containing two product bottles each identified "448892 ES 12/3/07". An FDA 525 is attached to the sample.					
8.	NET CON- TENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED <input checked="" type="checkbox"/> UNITS EXAMINED	DECLARE/UNIT 100 tablets AMOUNT FOUND _____ % OF DECLARED _____	9.	LABEL- ING 1 ORIGINAL(S) SUBMITTED ____ COPIES SUBMITTED <input type="checkbox"/> NONE
10. SUMMARY OF ANALYSIS Container: Round, opaque, white, plastic bottle with a similar, screw-on, safety cap. Safety-seal beneath cap is intact. Bottle is approximately 4 cm. in diameter and 7.5 cm. in height. Labeling: Commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside bottle. Code: " Control No.: 70664A1 " and " Exp. Date: AUG 09 " printed on each bottle label. Product: Round, biconvex, solid, white tablet. Tablet is unscored on one side with no markings. Opposite side is 1/2-scored with markings "B" and "146". Tablet is approximately 7 mm. in diameter. Analysis: Identification, Dissolution, and Content Uniformity. Method: USP 30 - NF 25, p. 1943. Results: See general continuation sheet page 2.					
11. RESERVE SAMPLE Original plastic bag containing one open and one intact product bottle. Bag is officially sealed " 448892 4/29/08 Valentino Fiorella Analyst". Open bottle is identified " 448892 VF 2/4/08 " and " DPD 4/25/08 ". Sample returned to the sample custodian.					
12.a. ANALYST SIGNATURE (Broke Seal <input checked="" type="checkbox"/>) <i>Valentino Fiorella</i>			13. WORK- SHEET CHECK	a. BY <i>S. Mathew</i>	
b. <i>Dongping Dai</i>				b. DATE 4/29/08	
c.				14. DATE REPORTED 4/29/08	

FORM FDA 431 (5/84)

ATTACHMENTS : A (pp. 1 - 20), B

PREVIOUS EDITION IS OBSOLETE

PAGE / OF // PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
<p><u>RESULTS:</u></p> <p><u>Identification</u></p> <p>The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation. <u>Complies</u></p> <p><u>Content Uniformity</u> (See computer printout pages 6 - 7 for complete results)</p> <p>Range: <u>95.2</u> % to <u>99.5</u> %; Average (X): <u>97.8</u> %; RSD: <u>1.3</u> %; s: <u>1.23</u></p> <p>Acceptance Value (AV) = <u>3.7</u> %</p> <p>(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)</p> <p><u>Dissolution</u> (See least squares line fitting page // for complete results)</p> <p>Range: <u>87.4</u> % to <u>101.4</u> % ; Avg.: <u>92.5</u> %</p> <p>(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))</p>		
ANALYST(S) <u>Valentino Firella</u>	ANALYST NO. 113	PAGE <u>2</u> OF <u>11</u> PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Fiorella</i>	ANALYST NO. 113	PAGE 3 OF 11 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Fioell</i>	ANALYST NO. 113	PAGE 4 OF 11 PAGES

Sheet

Sample No. 448892

Statistical Analysis of Data:

Standard Solution 1 (CCV)

02/12/2008

Relative STD Deviation	0.29 %	
Standard Deviation	3887.34041	
Average (mean)	1358880	
Number of entries	5	
Range	1353155 To 1363224	

Data Entered:

1353155
1358820
1361570
1357631
1363224

Analyst(s)

Valentino Fiorell

Analyst No.
113

Page 5 of 11 Pages

General Continuation
Sheet

Product: Digoxin Tablets

Sample No. 448892

Content Uniformity

02/13/2008

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	100
Sample Dilution	10

Data Entered:

Unit #1	1371299✓	STD #1	1358880
Unit #2	1357145✓	Blank	0
Unit #3	1361144✓		
Unit #4	1375129✓		
Unit #5	1333663✓		
Unit #6	1366084✓		
Unit #7	1377397✓		
Unit #8	1375557✓		
Unit #9	1389731✓		
Unit #10	1394609✓		

CONTENT UNIFORMITY RESULTS:

	FOUND (mg/tablet)	DECLARED	% of DECLARED
UNIT #1	0.245	0.25	97.8
UNIT #2	0.242	mg/tablet	96.8
UNIT #3	0.243		97.1
UNIT #4	0.245		98.1
UNIT #5	0.238		95.2
UNIT #6	0.244		97.5
UNIT #7	0.246		98.3
UNIT #8	0.245		98.1
UNIT #9	0.248		99.2
UNIT #10	0.249		99.5
AVG.	0.244		97.8

OFFICIAL LIMITS: 90.0 % TO 105.0 %
 No. of Units Examined 10
RANGE 95.2 % TO 99.5 % of Declared
 UNITS >=85 BUT <=115 % of Avg. Limit : 10
 UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit : 0
 UNITS <75 OR >125 % of Avg. Limit : 0
REL. STD. DEV. : 1.3 LIMIT <= 6.0%

$$\text{mg/unit} = (R_{\text{spl}} * \text{std_wt} * \text{spl_dil}) / (R_{\text{std}} * \text{std_dil} * 1 \text{ unit})$$

Analyst(s)

*Valentino Storch*Analyst No.
113

Page 6 of 11 Pages

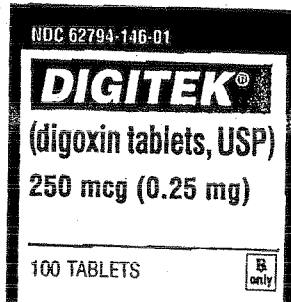
Digoxin Tablets (0.25 mg)

Spl.# 448892

2/4/08

VF

Labeling



Each tablet contains:
Digoxin, USP 250 mcg (0.25 mg)
For indications, dosage, precautions,
etc., see accompanying package insert.

C
O
S
P
T
R
E

Sample # 448892

2/4/08
VF

EB

12/3/07

dry

old



N
3

62794-146-01 3

Distributed by:
BERTEK PHARMACEUTICALS INC.
Sugar Land, TX 77478 USA

Manufactured by:
AMIDE PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, NJ 07424 USA

Control No.: 70664A1
Exp. Date: AUG 09

8067-01

RBK146A1

Sheet

Product: Digoxin Tablets (0.25 mg)

Sample No. 448892

Statistical Analysis of Data:

Content Uniformity
Standard Deviation

02/13/2008

Relative STD Deviation	1.26 %		
Standard Deviation	1.23		
Average (mean)	97.76		
Number of entries	10		
Range	95.2	To	99.5

Data Entered:

97.8
96.8
97.1
98.1
95.2
97.5
98.3
98.1
99.2
99.5

Analyst(s)

*Valentino F. Willh*Analyst No.
113

Page 7 of 11 Pages

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 8 OF 11 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 9 OF 11 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 448892
ANALYST(S) <i>Valentina Fiorelli</i>	ANALYST NO. 113	PAGE 10 OF 11 PAGES

General Continuation
Sheet

Product: Digoxin Tablets (0.25 mg)

Sample No.

448892

Least Squares Line Fitting

04/25/2008

The Line Fitting used is $Y = mX + b$ with $m =$ 0.03663and $b =$ -0.0548

Correlation Coefficient = 0.99984

Data Entered:

X	Y	LSLF y	% Deviation
20	0.661	0.6778	2.479
40	1.444	1.4104	2.382
60	2.133	2.143	0.467
80	2.862	2.8756	0.473
100	3.615	3.6082	0.188

Extrapolated Data:

	X	Y
Tab 1	88.9	3.203
	92.7	3.341
Tab 2	89.7	3.230
	90.4	3.258
Tab 3	103.0	3.719
	99.8	3.600
Tab 4	88.5	3.188
	86.2	3.101
Tab 5	91.7	3.304
	91.3	3.288
Tab 6	95.5	3.445
	91.8	3.309

Analyst(s)

Dongping Dai

Analyst No.
000

Page // of // Pages

ATTACHMENT A - Page 1 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Blank

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Blank-Rep2

Date: 02/12/2008 8:43:24 AM

Vial: 0

Injection Volume: 50 ul

Detector A

(218nm)

Pk #

Name

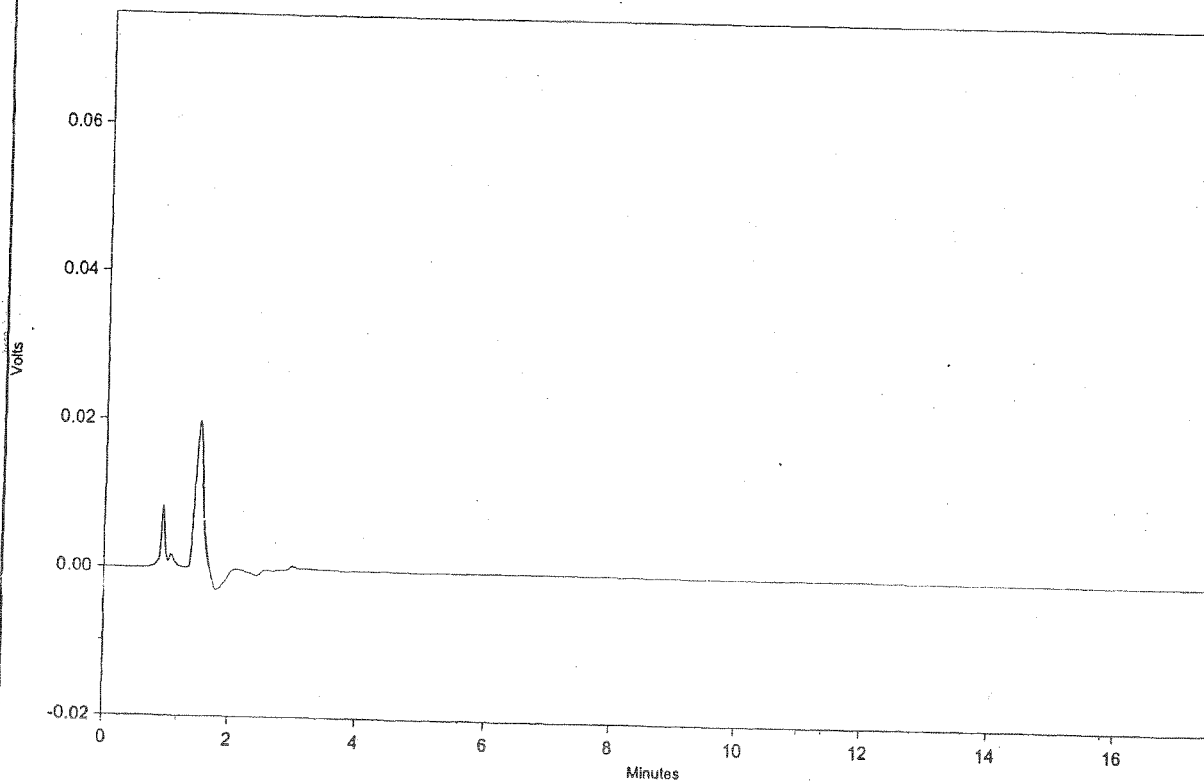
Retention
Time

Area

Height

Asymmetry

Resolution

Theoretical
plates

Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 2 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: System Suitability Solution

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\SysSuitSoln.

Date: 02/12/2008 9:02:22 AM

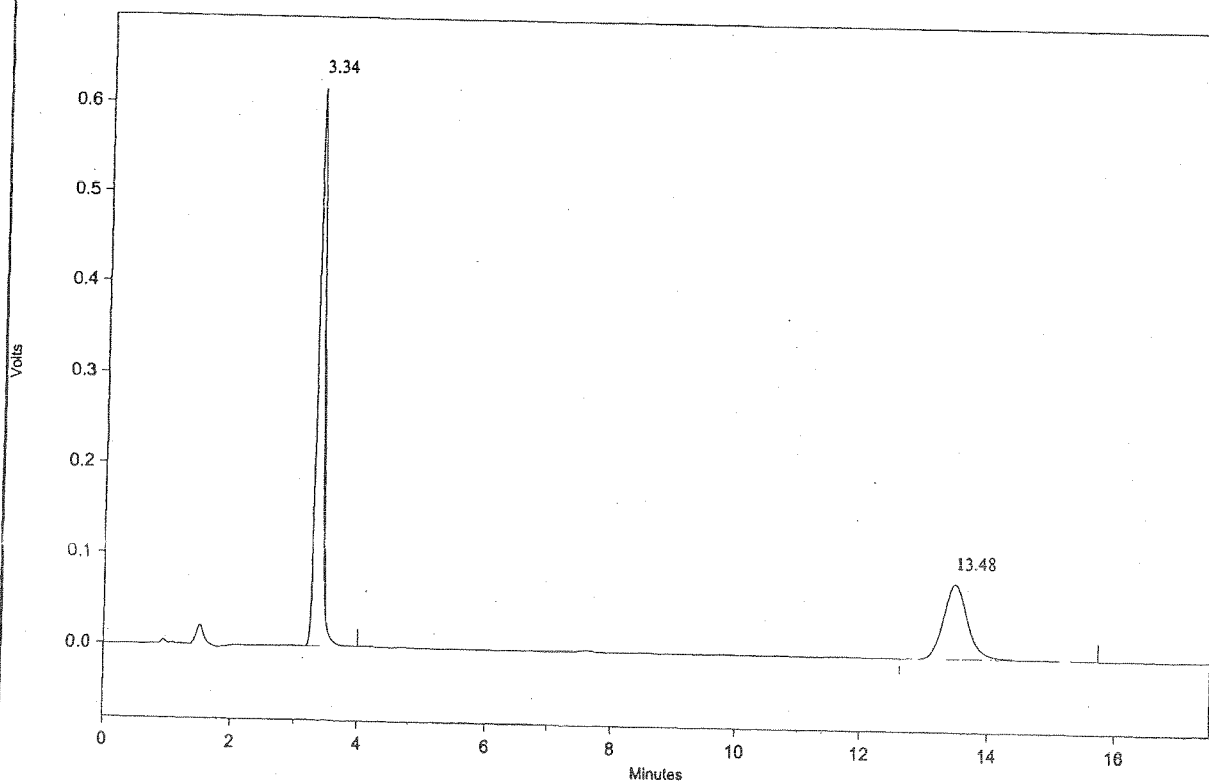
Vial: 1

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxigenin	3.34	4359467	618053	1.2	0.0	3134
2	Digoxin	13.48	2187380	82756	1.2	22.1	6321

Totals			6546847	700809			
--------	--	--	---------	--------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 3 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep1.

Date: 02/12/2008 9:24:02 AM

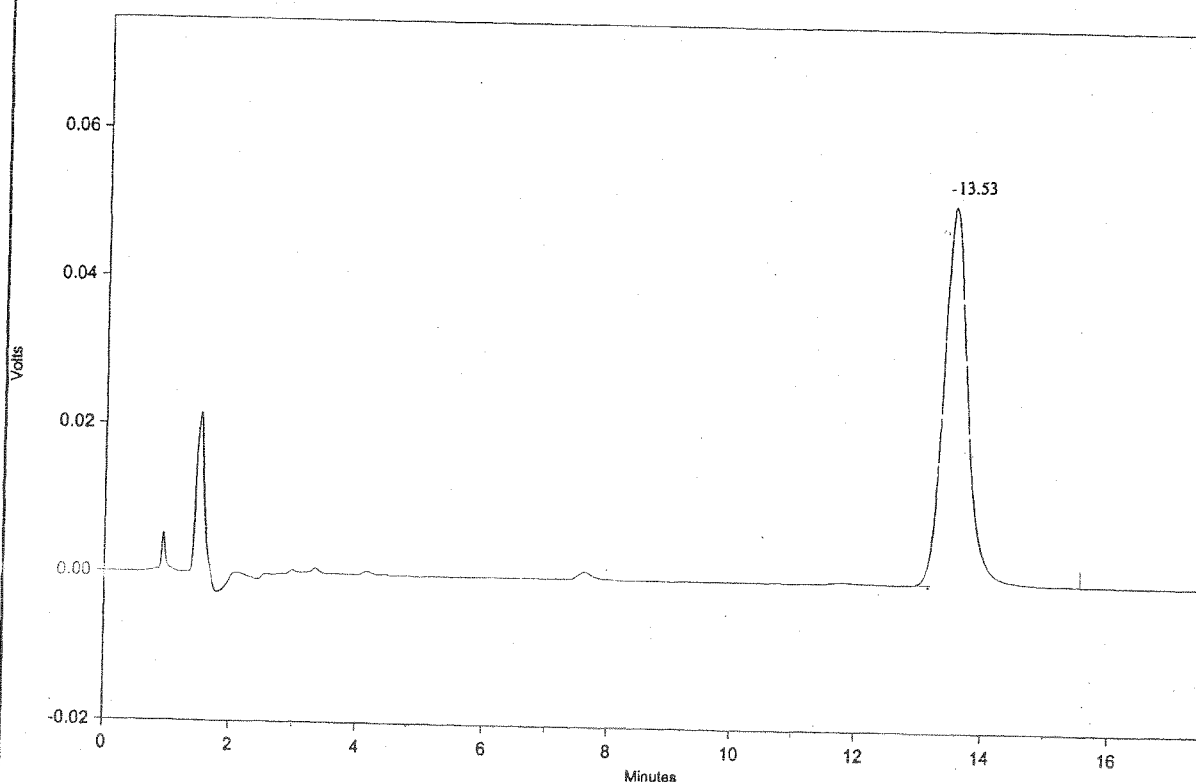
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.53	1353155	51094	1.2	0.0	6239

Totals			1353155	51094			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 4 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep2.

Date: 02/12/2008 9:43:01 AM

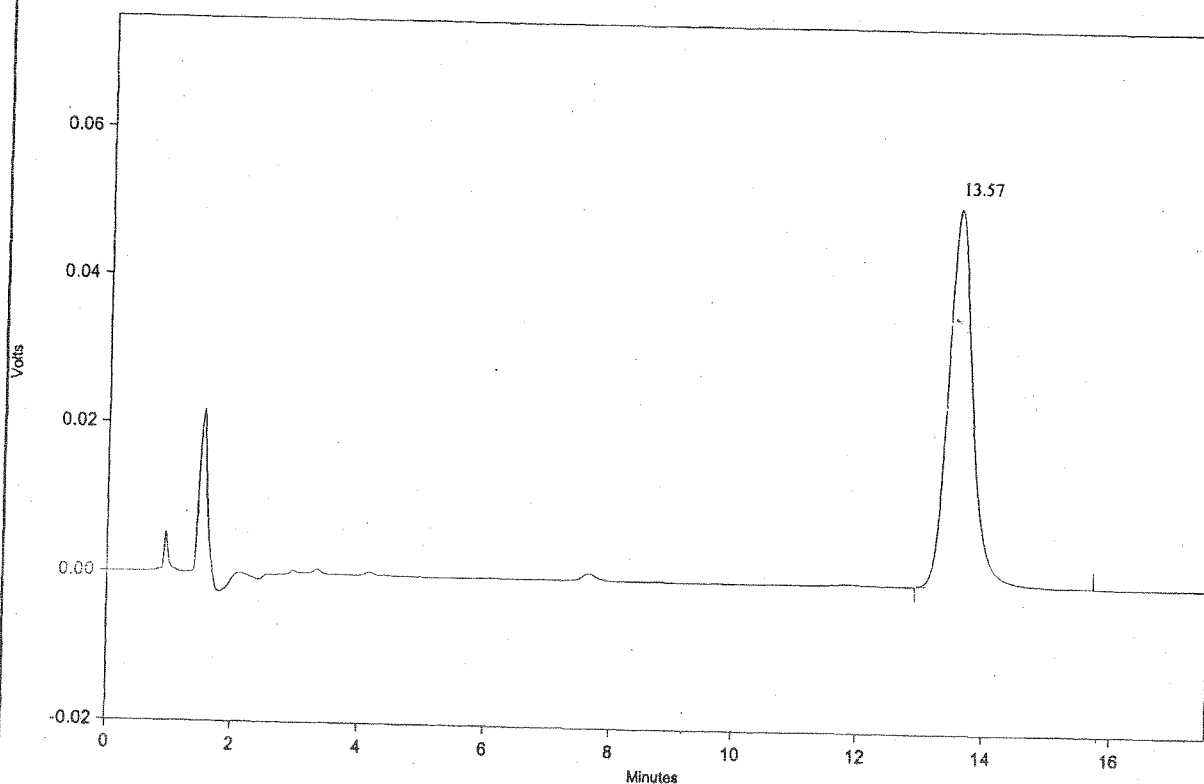
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.57	1358820	51067	1.2	0.0	6352

Totals			1358820	51067			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 5 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep3.

Date: 02/12/2008 10:01:55 AM

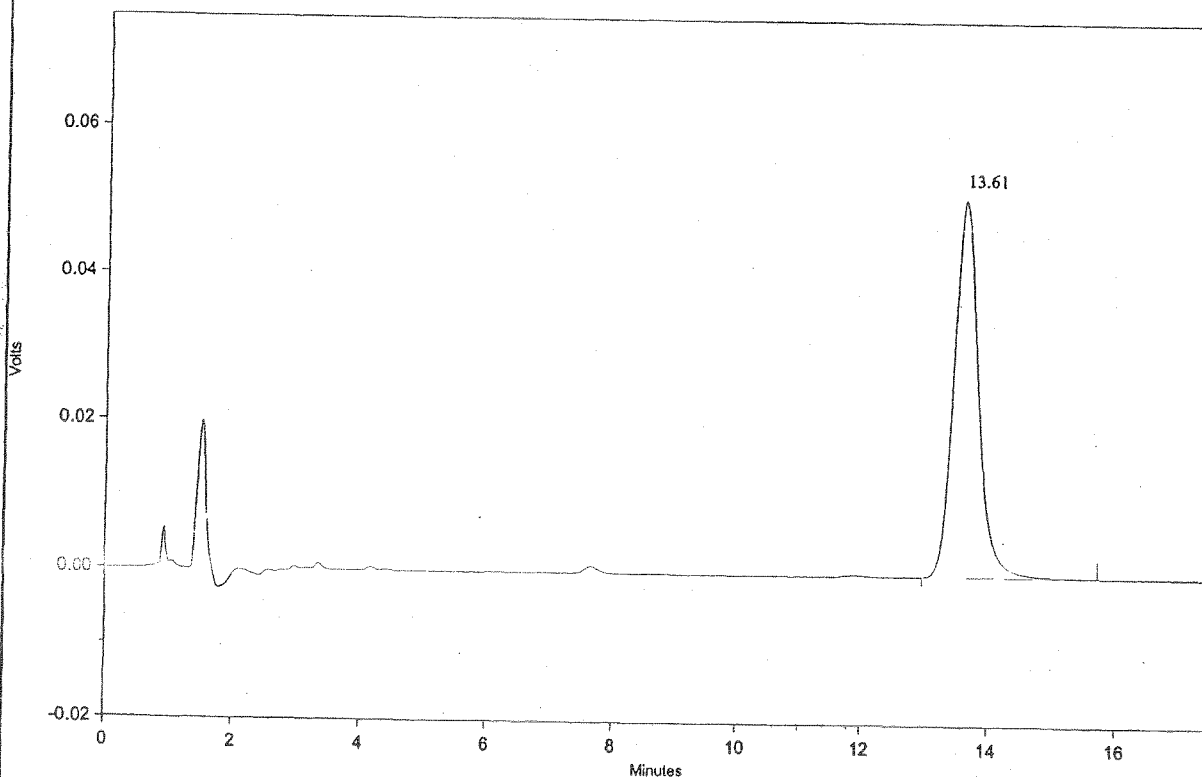
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.61	1361570	50892	1.2	0.0	6301

Totals			1361570	50892			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 6 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep4.

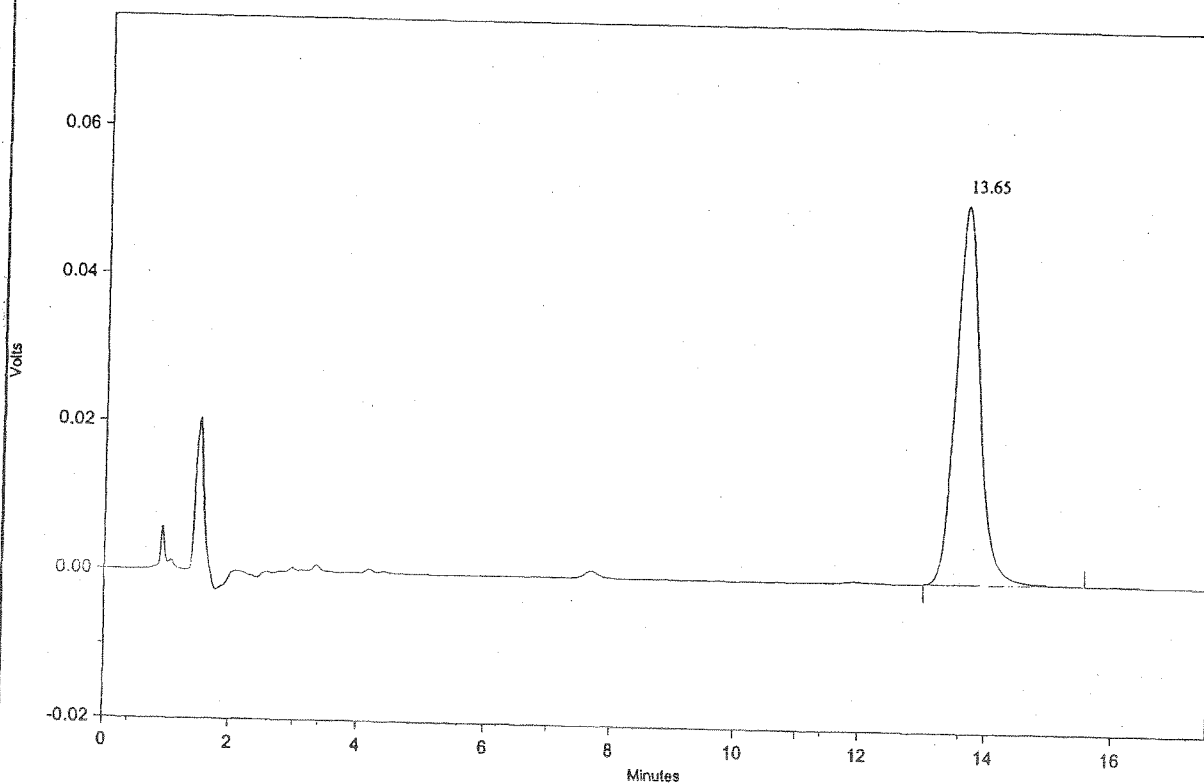
Date: 02/12/2008 10:20:57 AM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.65	1357631	51144	1.2	0.0	6418
Totals			1357631	51144			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 7 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln-Rep5.

Date: 02/12/2008 10:39:55 AM

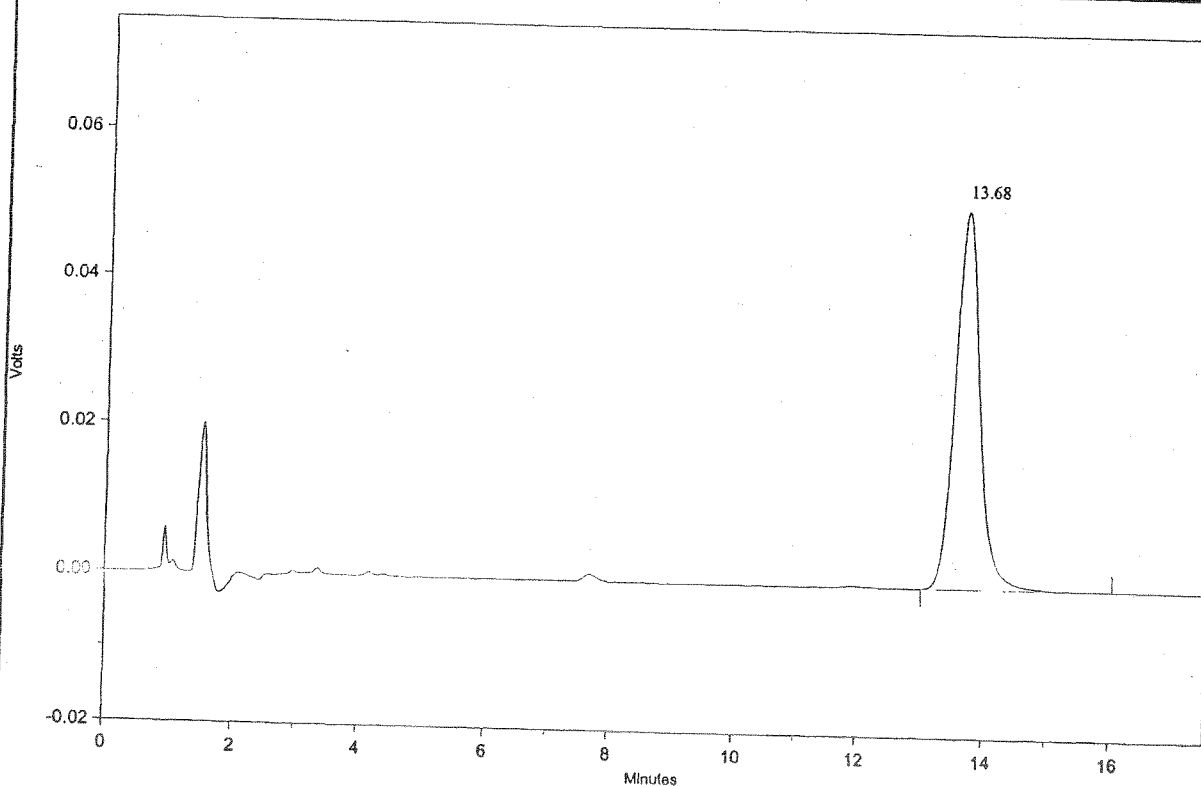
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.68	1363224	50989	1.2	0.0	6398

Totals			1363224	50989			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 8 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 2 (ICV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\CheckStd.

Date: 02/12/2008 10:58:52 AM

Vial: 3

Injection Volume: 50 ul

Detector A

(218nm)

Pk #

Name

Retention
Time

Area

Height

Asymmetry

Resolution

Theoretical
plates

1

Digoxin

13.70

1355271

50836

1.2

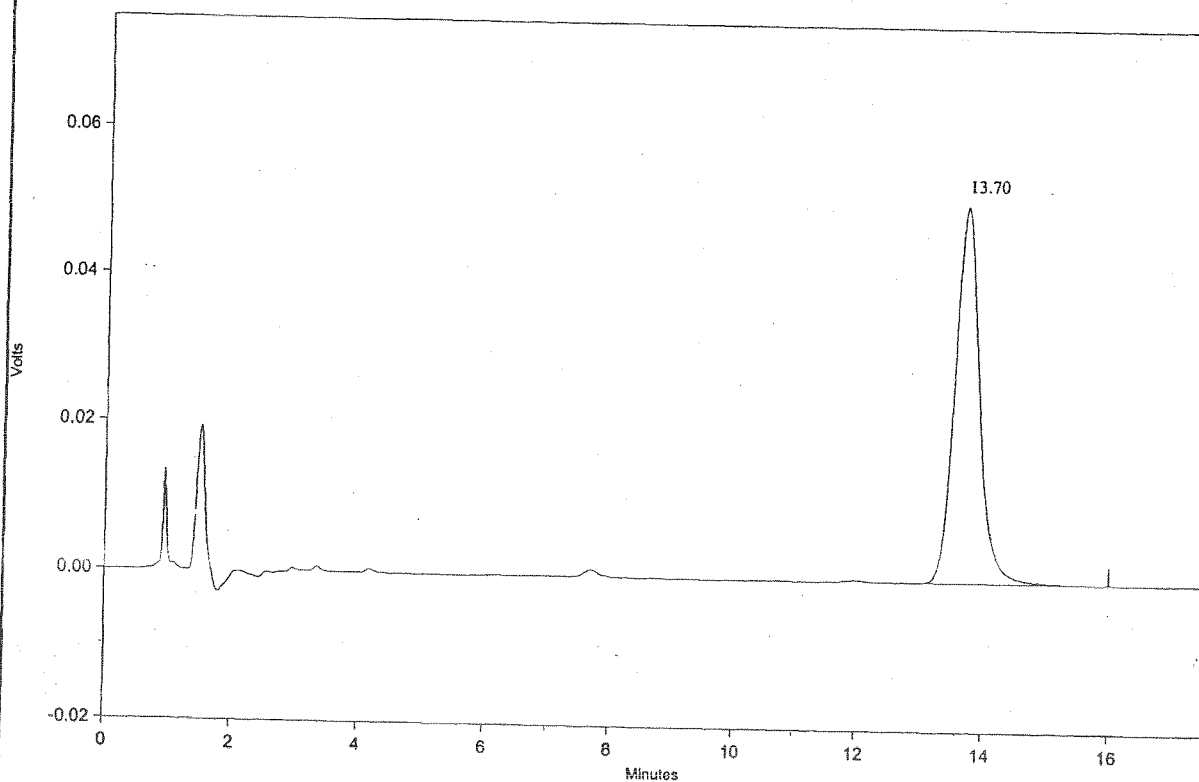
0.0

6402

Totals

1355271

50836



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 9 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 1

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab1

Date: 02/12/2008 11:21:25 AM

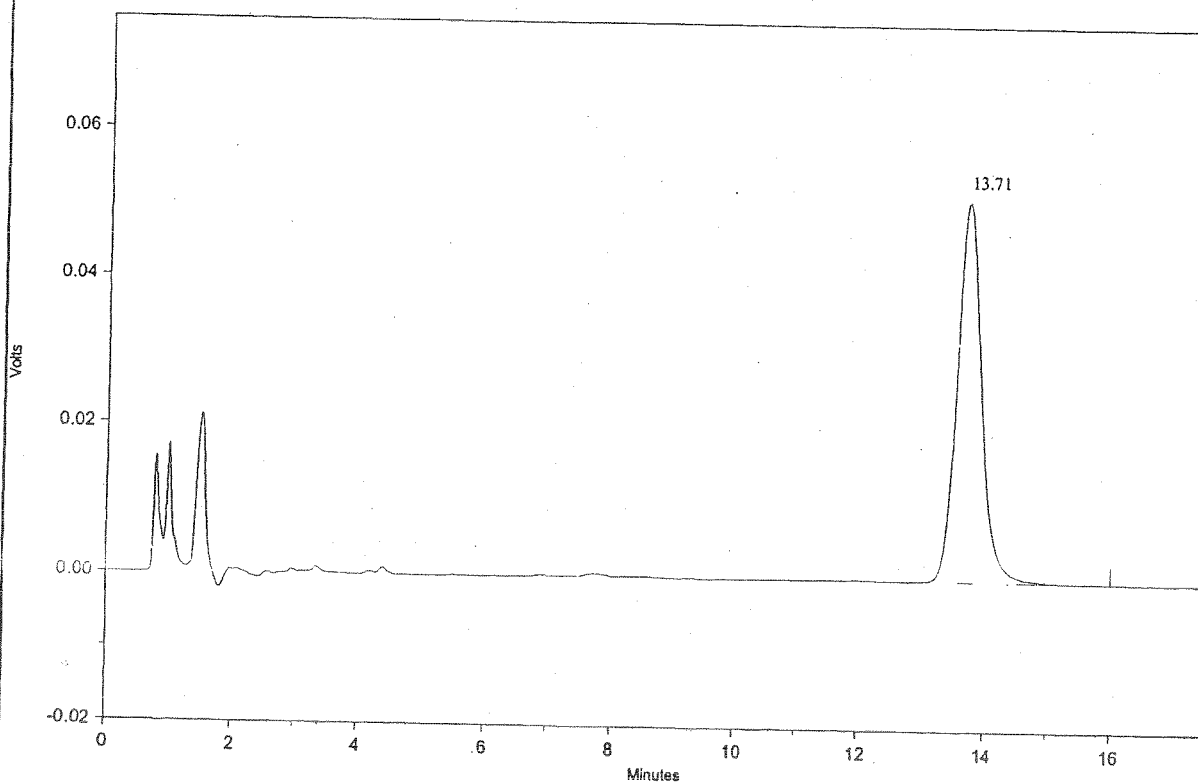
Vial: 4

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.71	1371299	51389	1.2	0.0	6415

Totals			1371299	51389			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 10 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 2

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab2

Date: 02/12/2008 11:42:46 AM

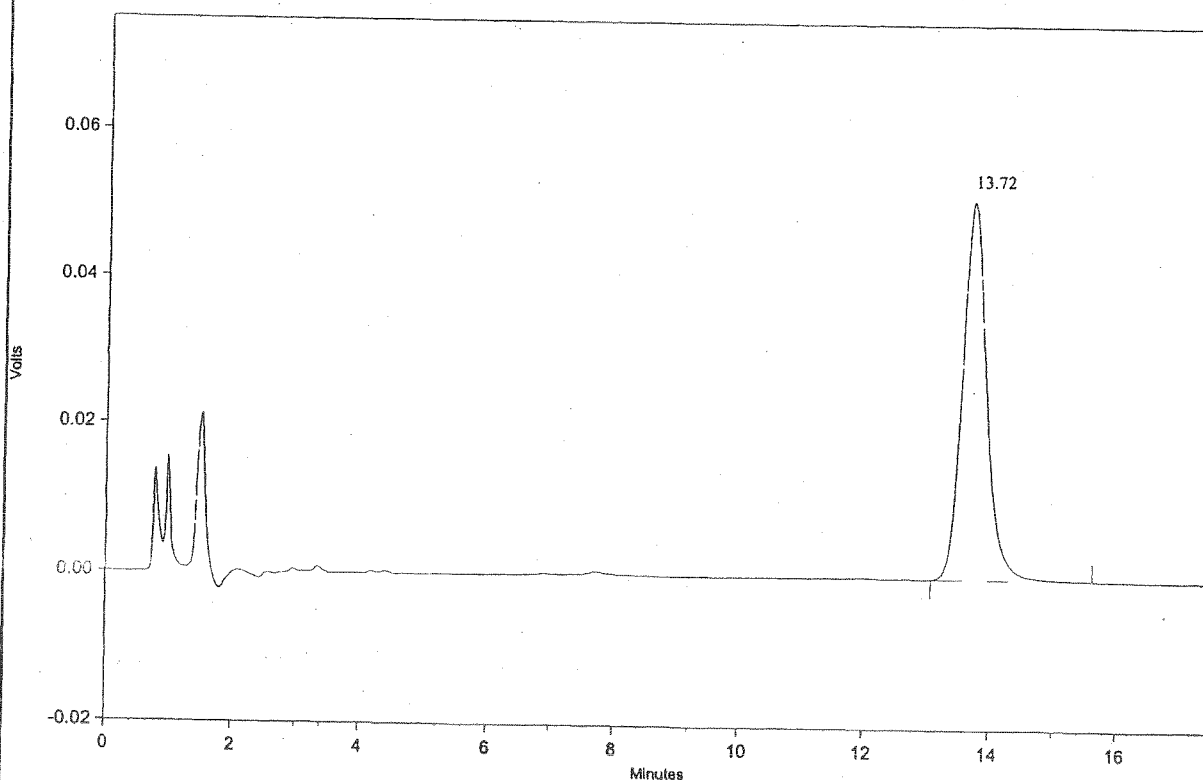
Vial: 5

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.72	1357145	51106	1.2	0.0	6272

Totals			1357145	51106			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 11 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 3

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab3

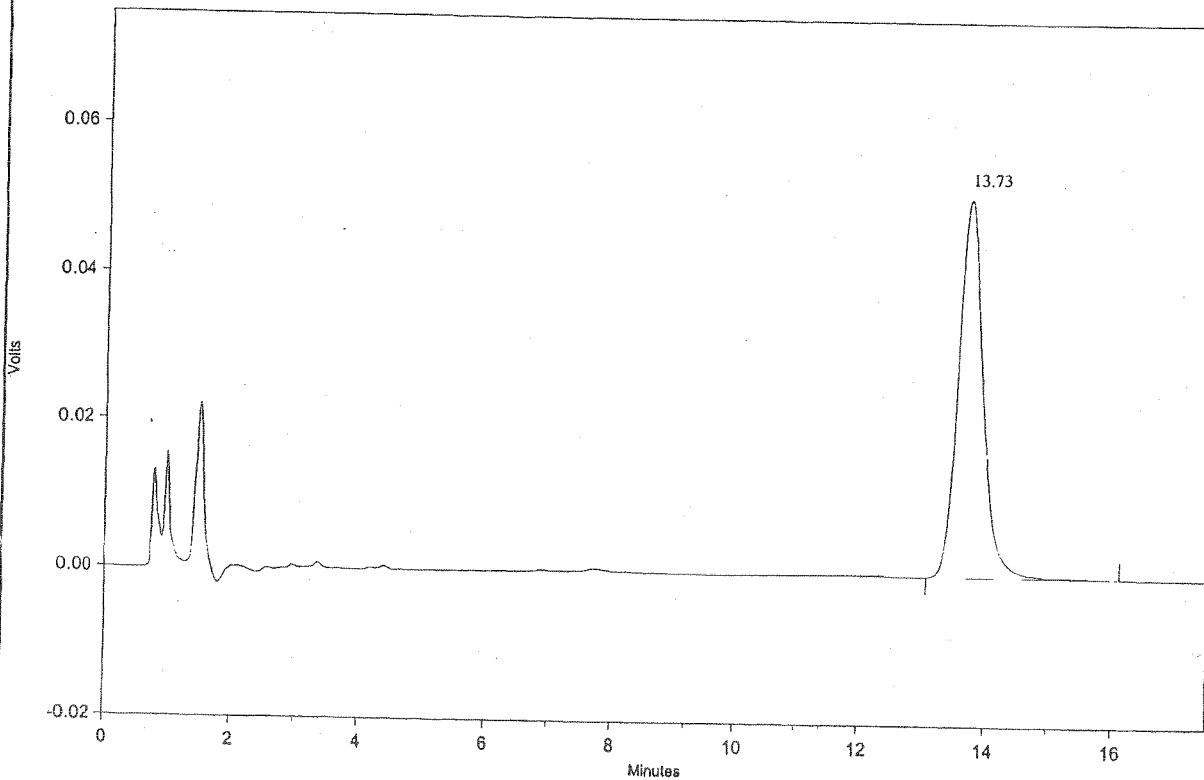
Date: 02/12/2008 12:01:44 PM

Vial: 6

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1361144	51054	1.2	0.0	6381
Totals			1361144	51054			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 12 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 4

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab4

Date: 02/12/2008 12:20:43 PM

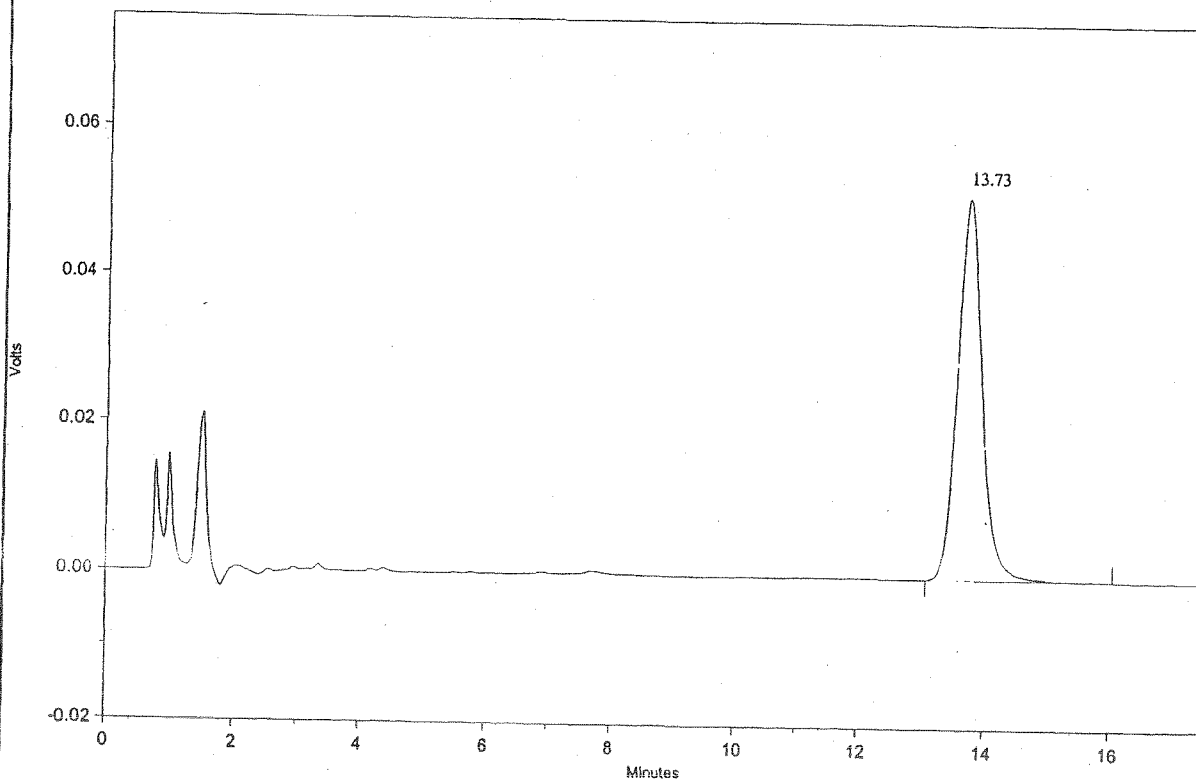
Vial: 7

Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1375129	51481	1.2	0.0	6361
Totals			1375129	51481			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 13 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 5

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab5

Date: 02/12/2008 12:39:41 PM

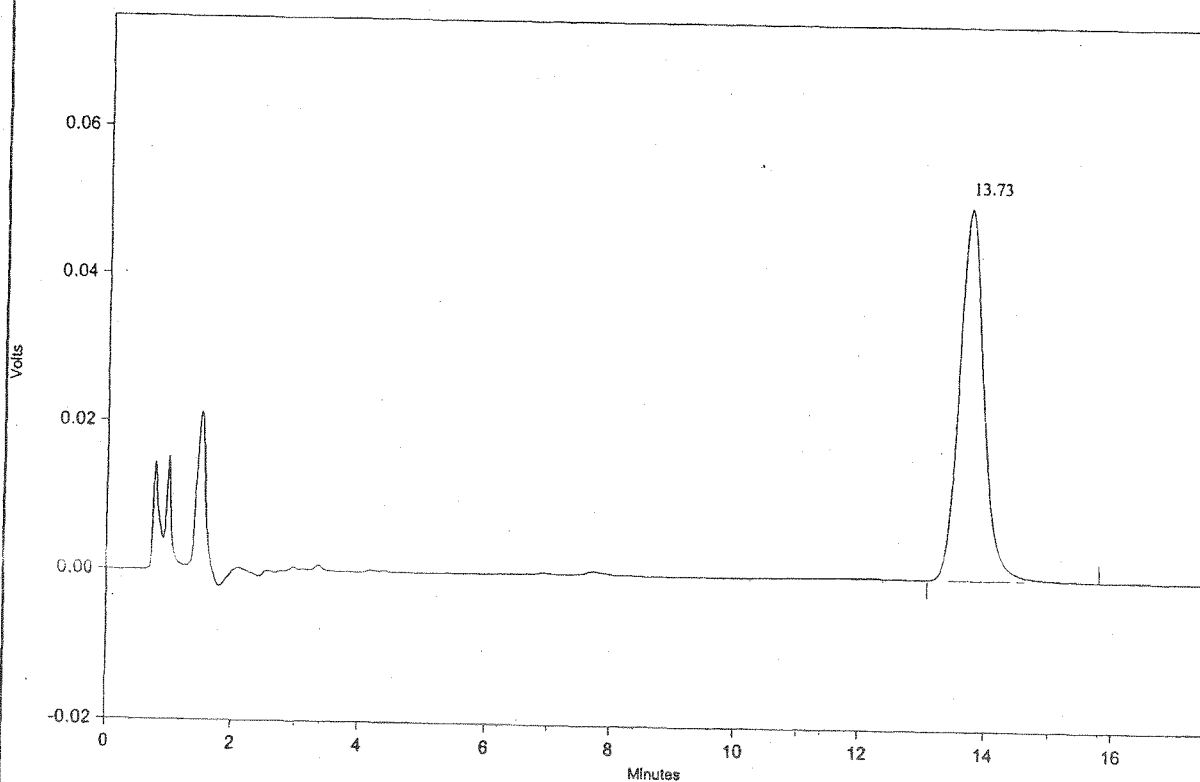
Vial: 8

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.73	1333663	50208	1.2	0.0	6439

Totals			1333663	50208			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 14 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln.6

Date: 02/12/2008 12:58:40 PM

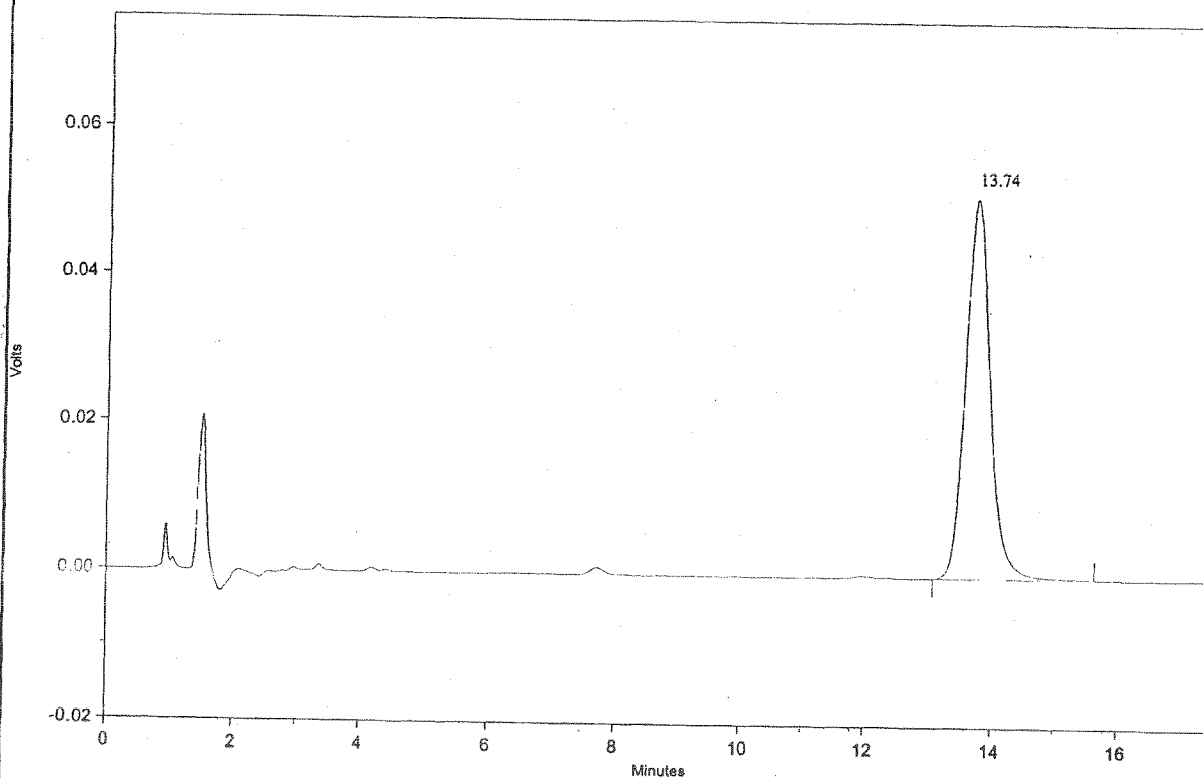
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.74	1360111	51218	1.2	0.0	6473

Totals			1360111	51218			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 15 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 6

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab6

Date: 02/12/2008 1:18:49 PM

Vial: 9

Injection Volume: 50 ul

Detector A

(218nm)

Pk #

Name

Retention
Time

Area

Height

Asymmetry

Resolution

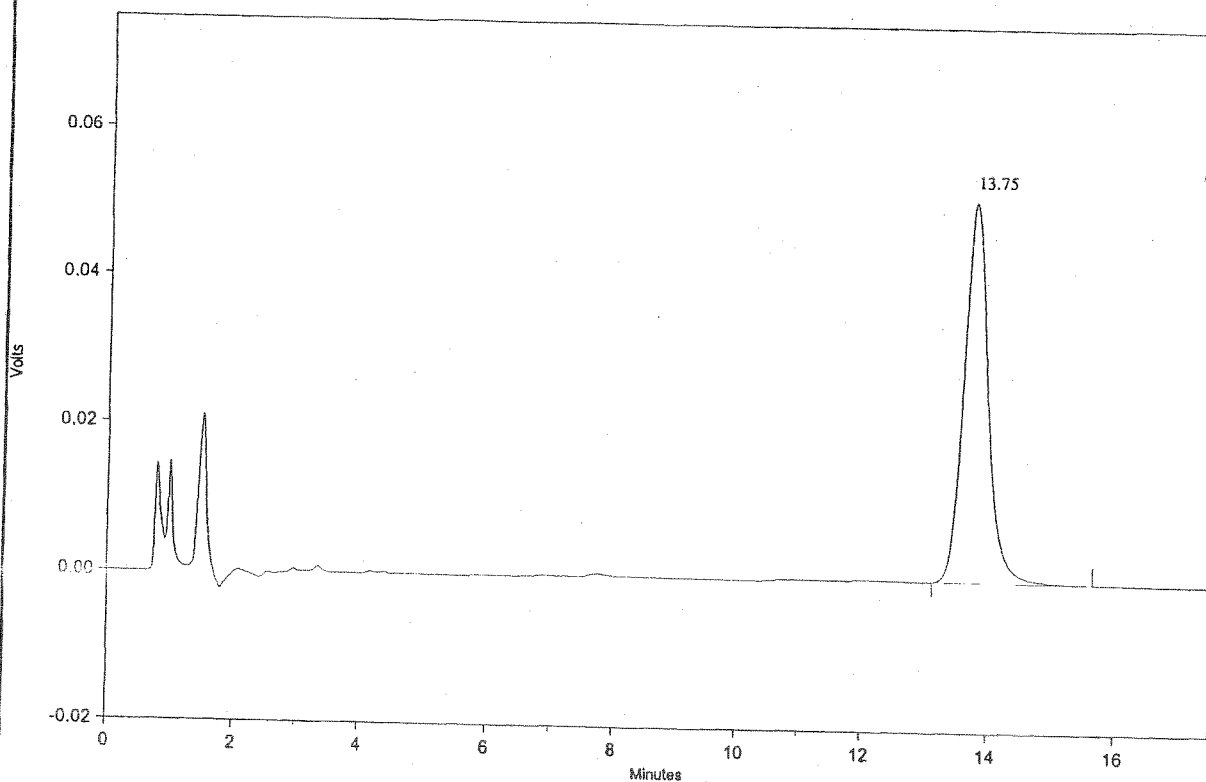
Theoretical
plates

1	Digoxin	13.75	1366084	51225	1.2	0.0	6269
---	---------	-------	---------	-------	-----	-----	------

Totals

1366084

51225



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 16 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 7

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab7

Date: 02/12/2008 1:37:47 PM

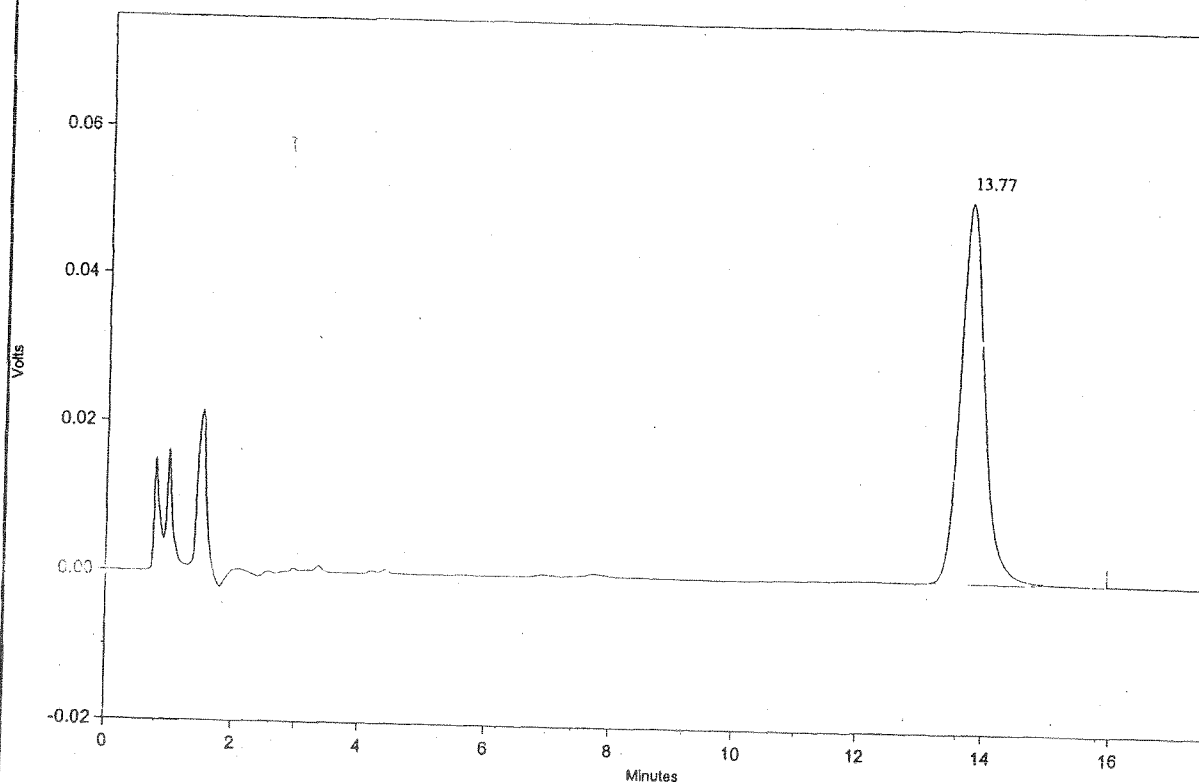
Vial: 10

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.77	1377397	51362	1.2	0.0	6373

Totals			1377397	51362			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 17 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 8

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab8

Date: 02/12/2008 1:58:03 PM

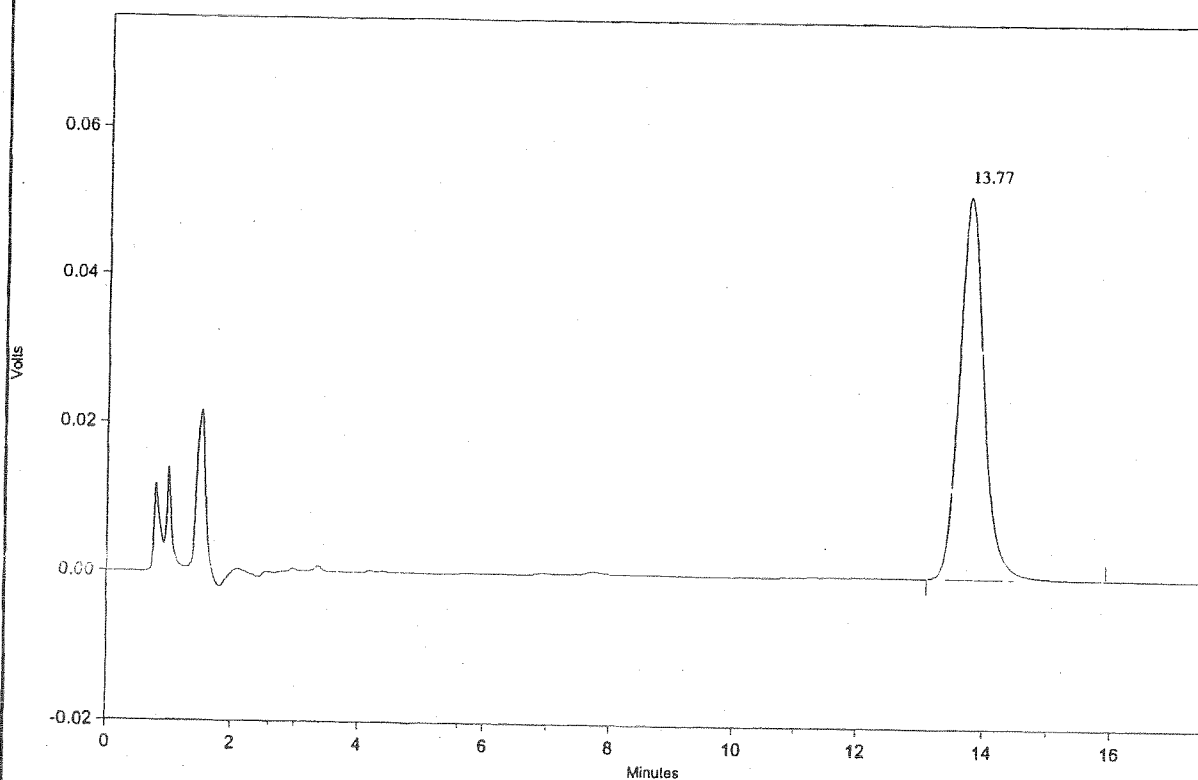
Vial: 11

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.77	1375557	51662	1.2	0.0	6467

Totals			1375557	51662			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 18 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 9

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab9

Date: 02/12/2008 2:17:02 PM

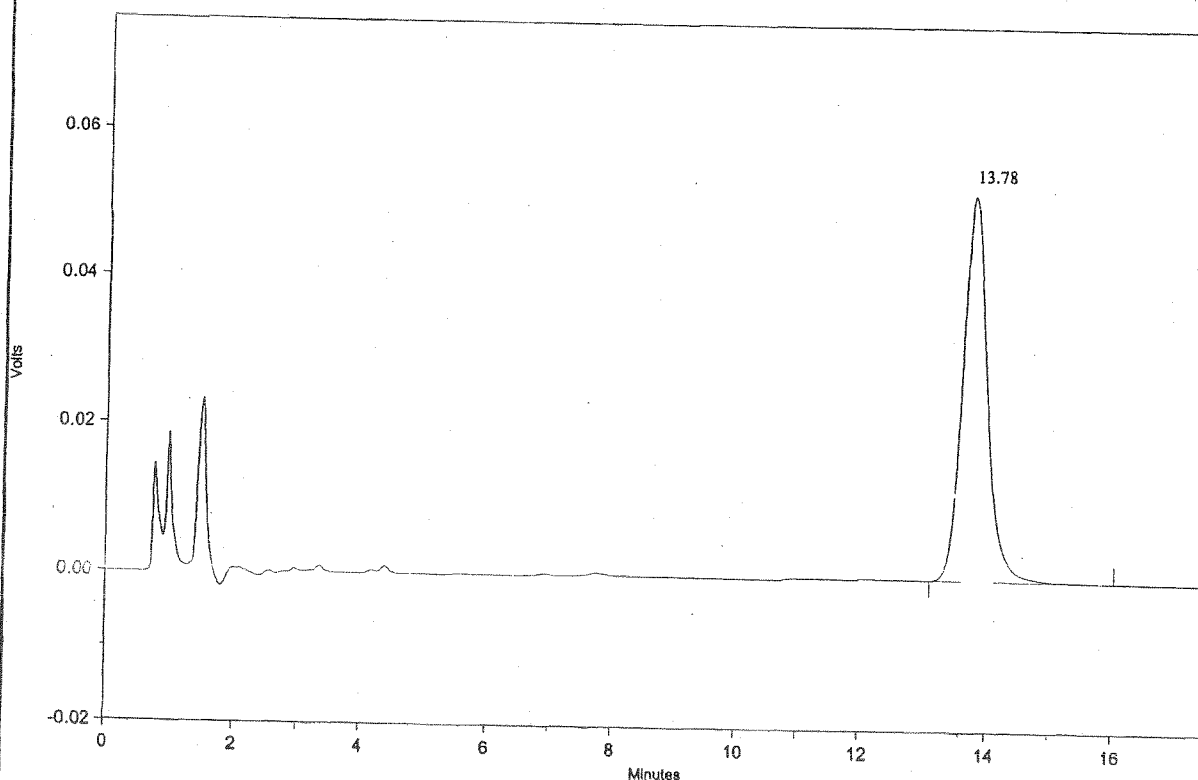
Vial: 12

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1389731	51926	1.2	0.0	6430

Totals			1389731	51926			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 19 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Tablet 10

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Tab10

Date: 02/12/2008 2:36:00 PM

Vial: 13

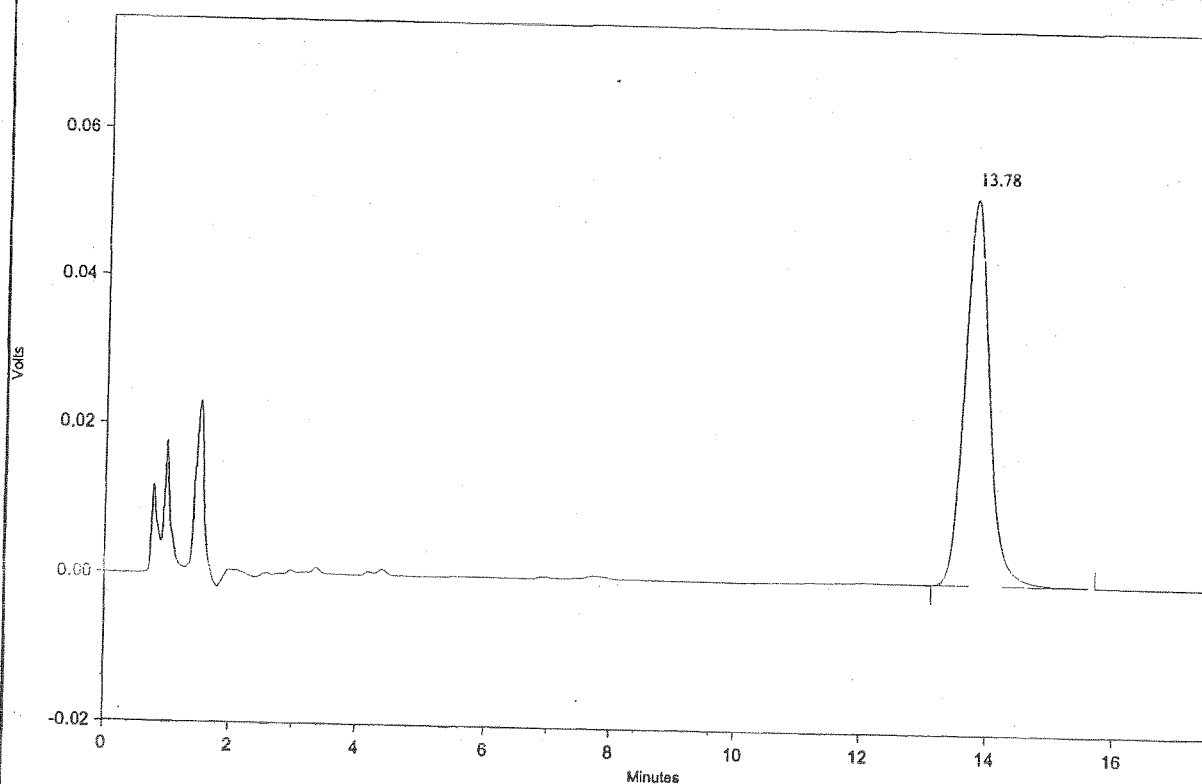
Injection Volume: 50 ul

Detector A

(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1394609	52172	1.2	0.0	6441

Totals			1394609	52172			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 20 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 448892

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\448892\Std.Soln.7

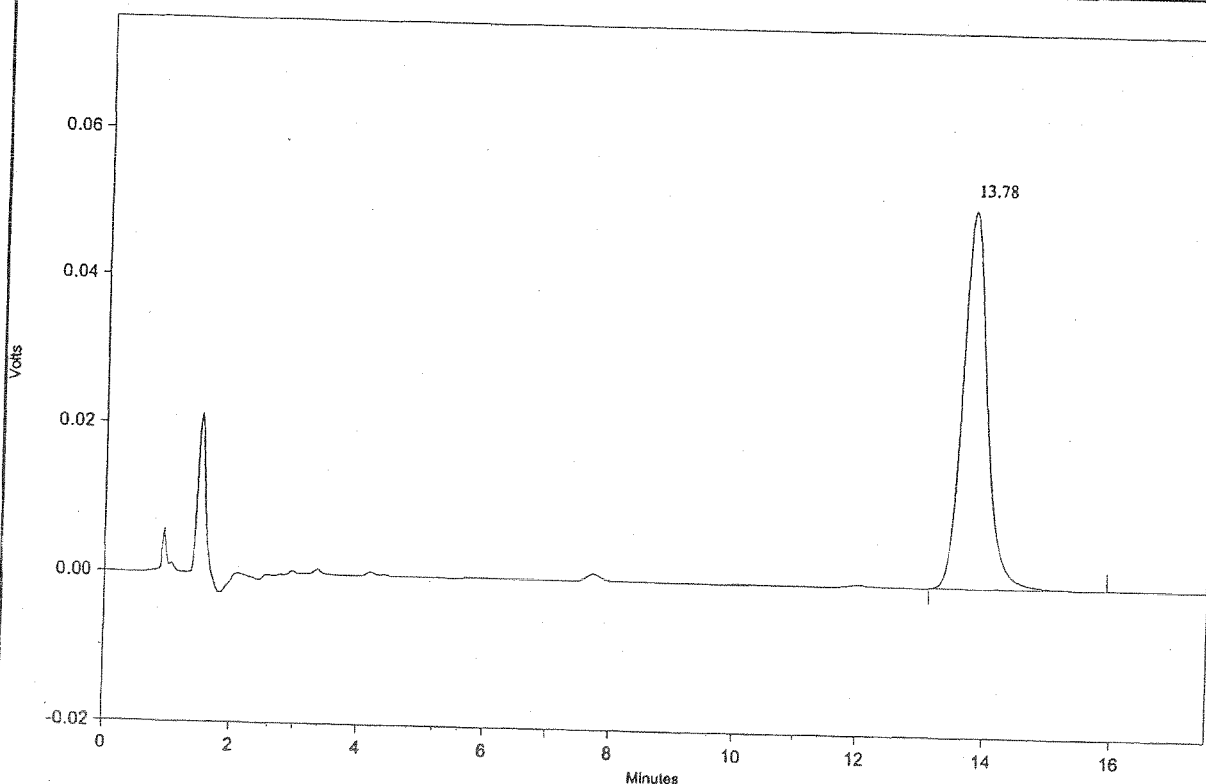
Date: 02/12/2008 2:54:53 PM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.78	1363877	51047	1.2	0.0	6461
Totals			1363877	51047			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 1/3/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

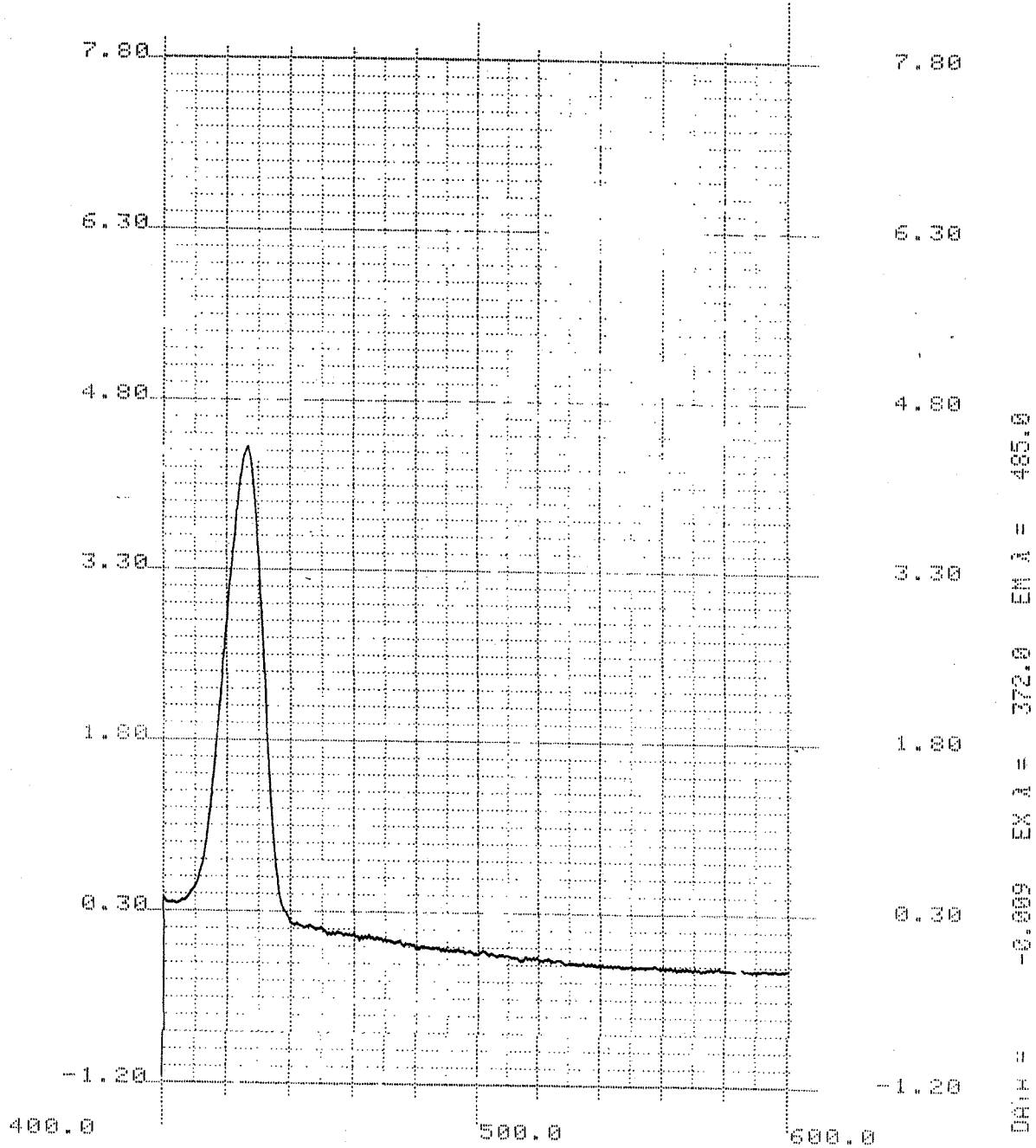
Attachment B

Digoxin Tablets (0.25 mg)

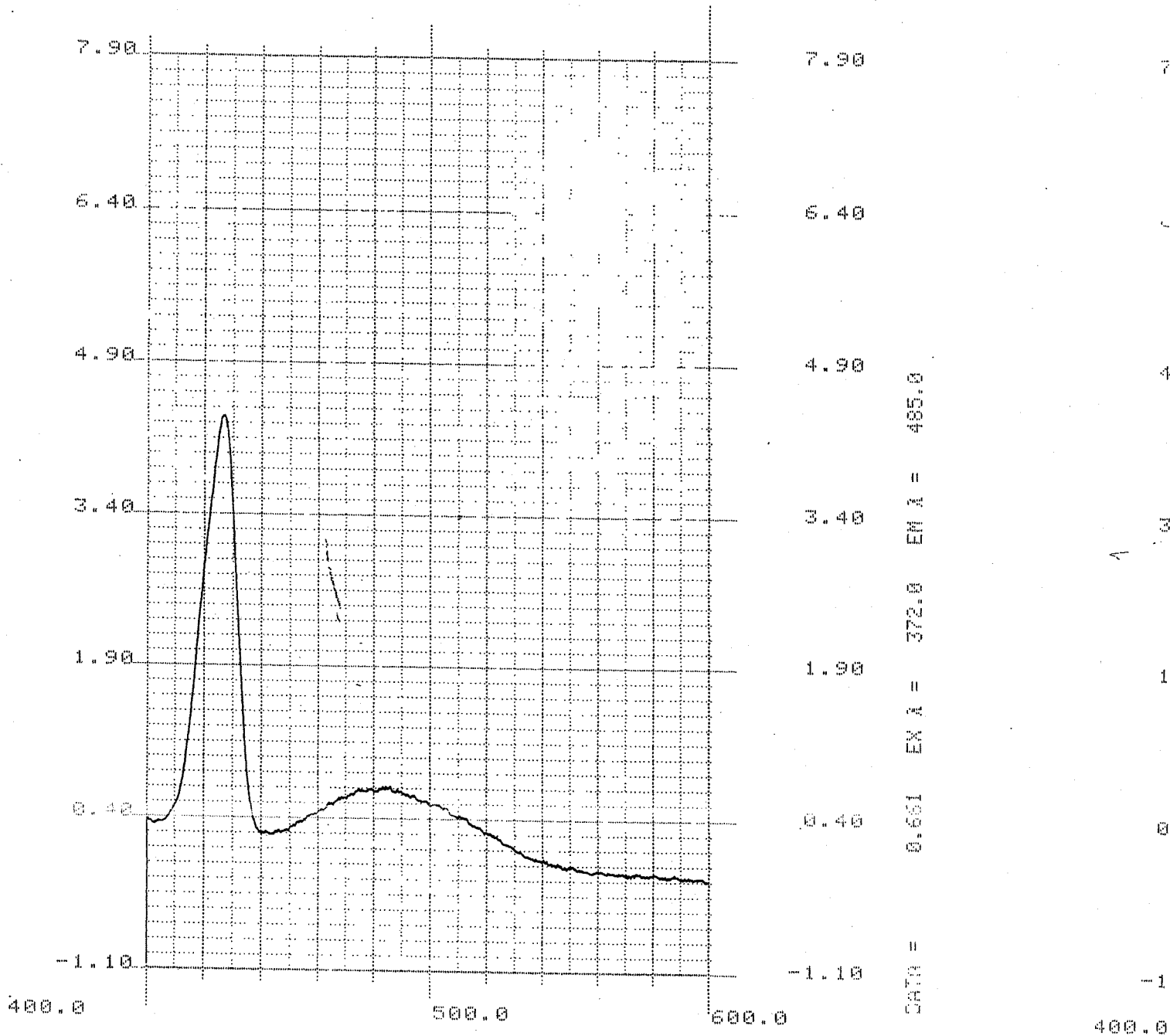
Spl.# 448892

4/25/08

Spl # 448892
4/25/08 bpo



Blank



std 20%

⊕ SHIMADZU CORPORATION CHART 200-91527

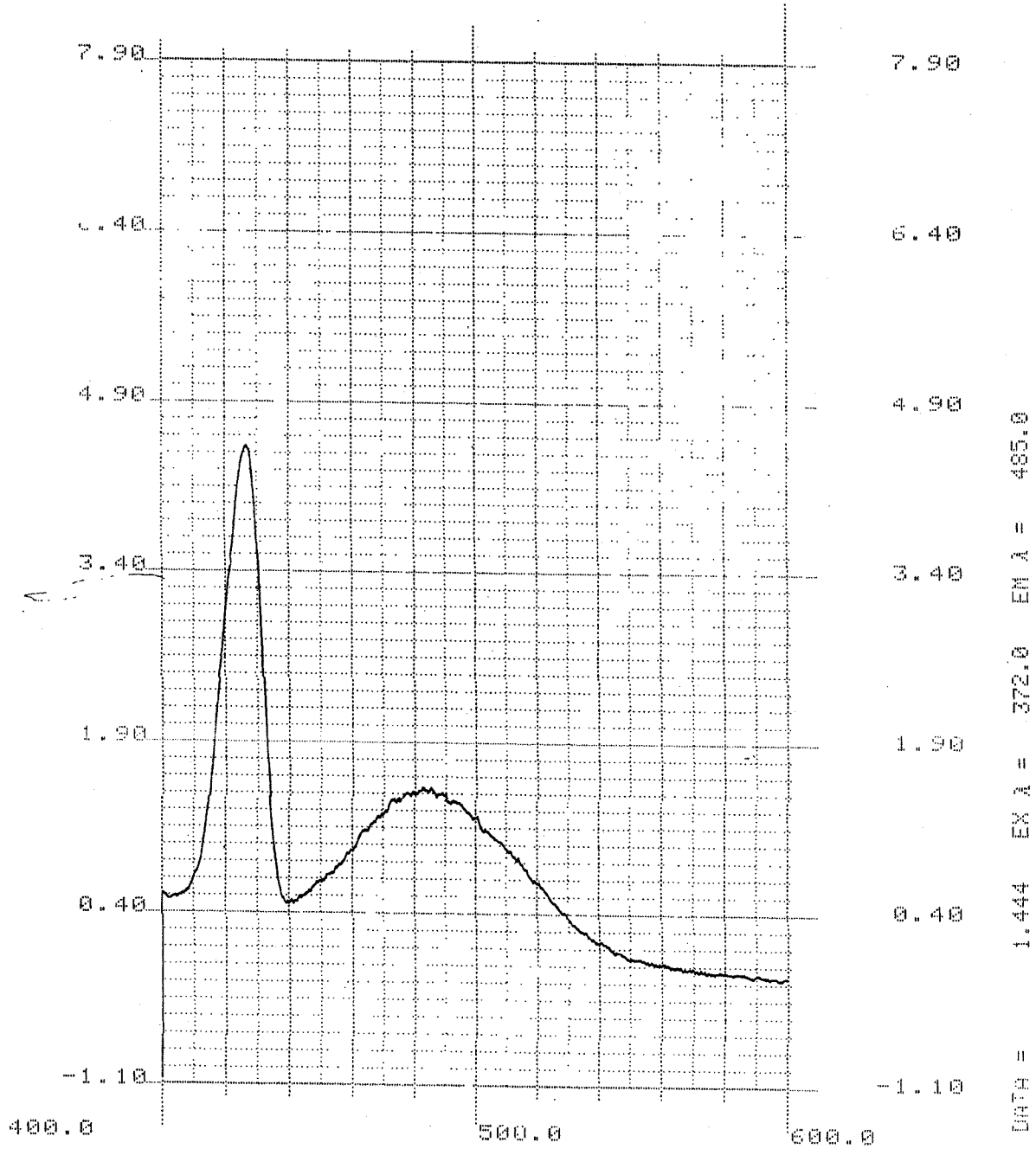
20%

Attachment B

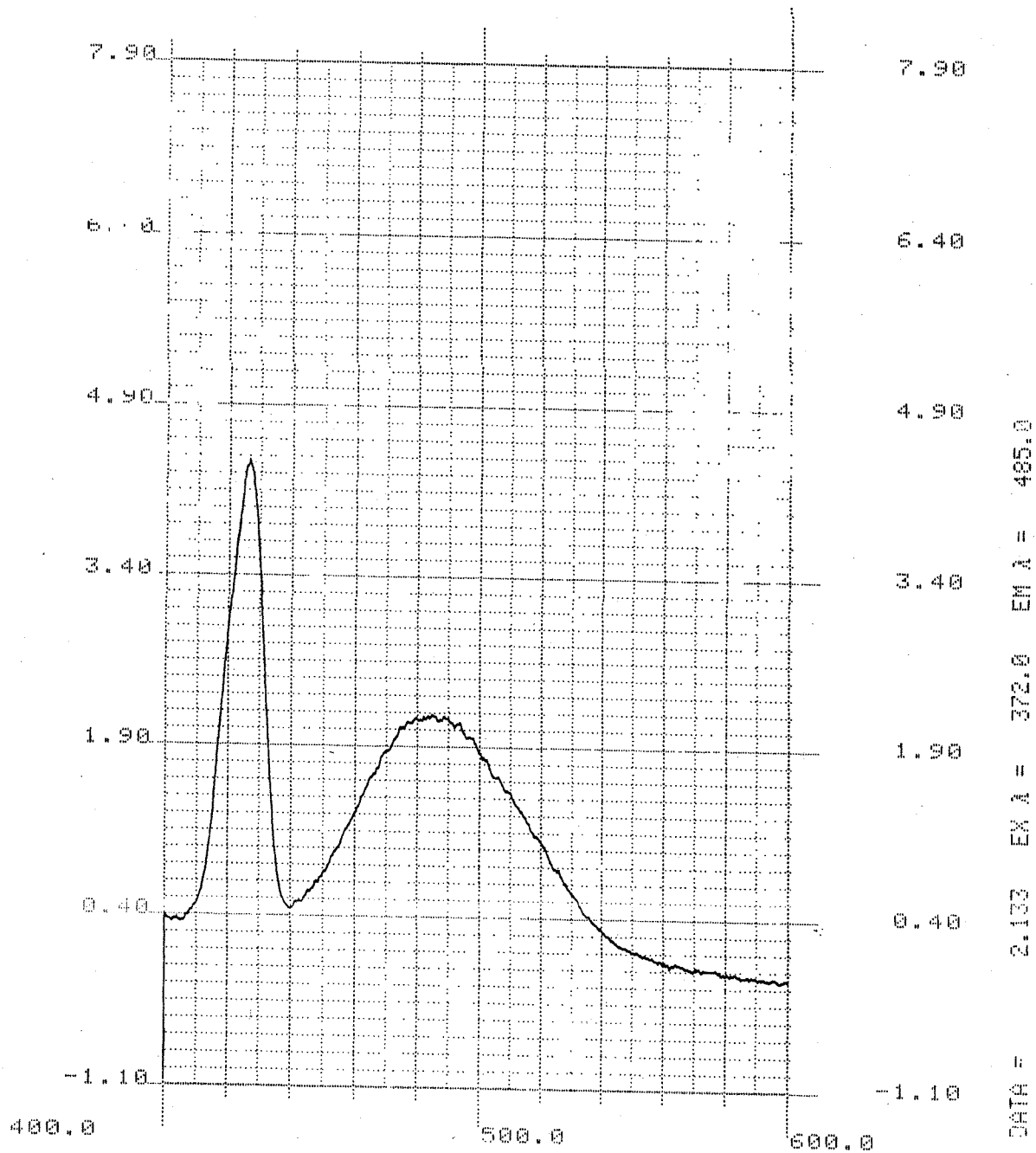
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



std 40%



std 60%

⊕ SHIMADZU CORPORATION CHART 200-91527

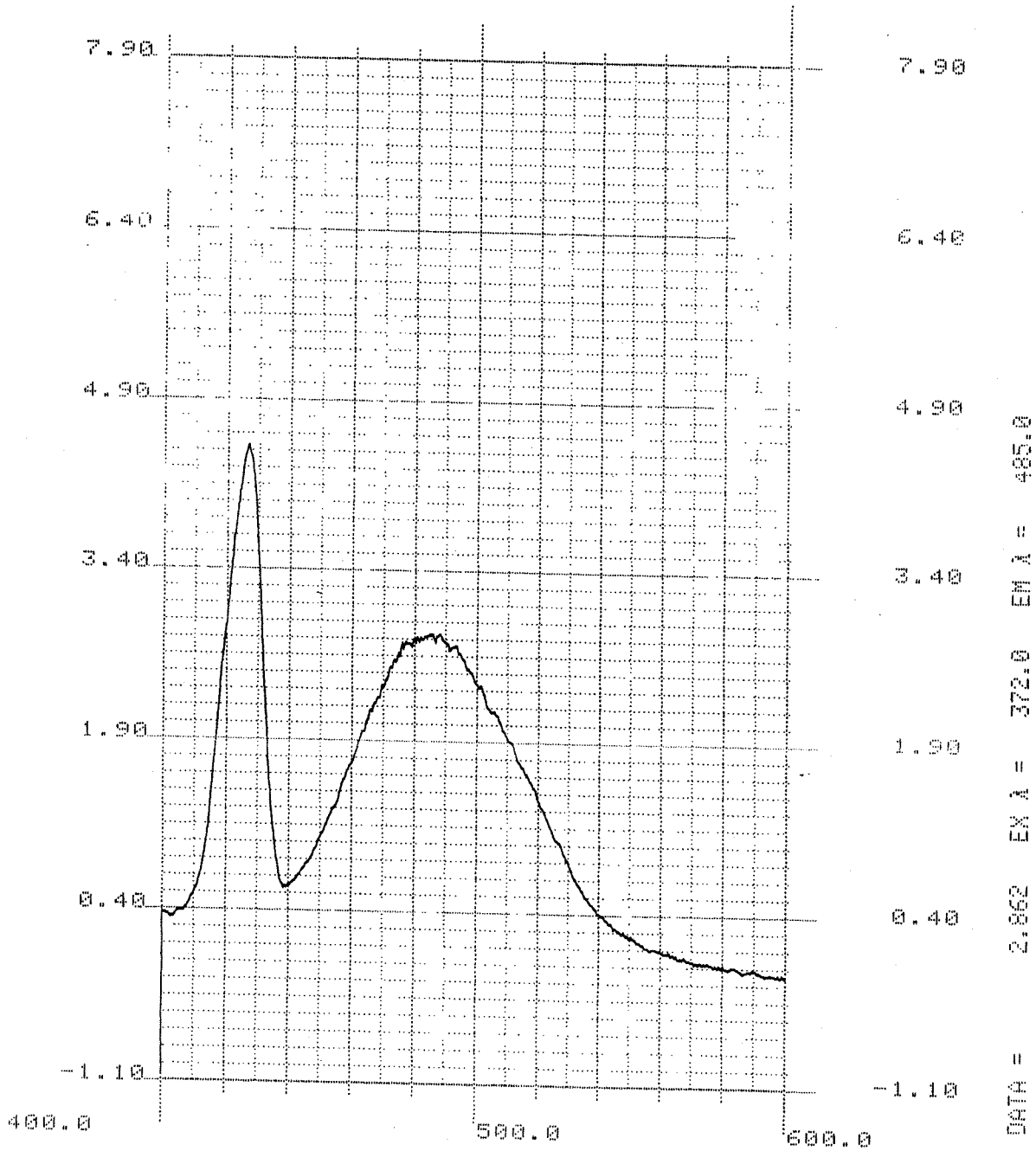
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Attachment B

Digoxin Tablets (0.25 mg)

Spl.# 448892

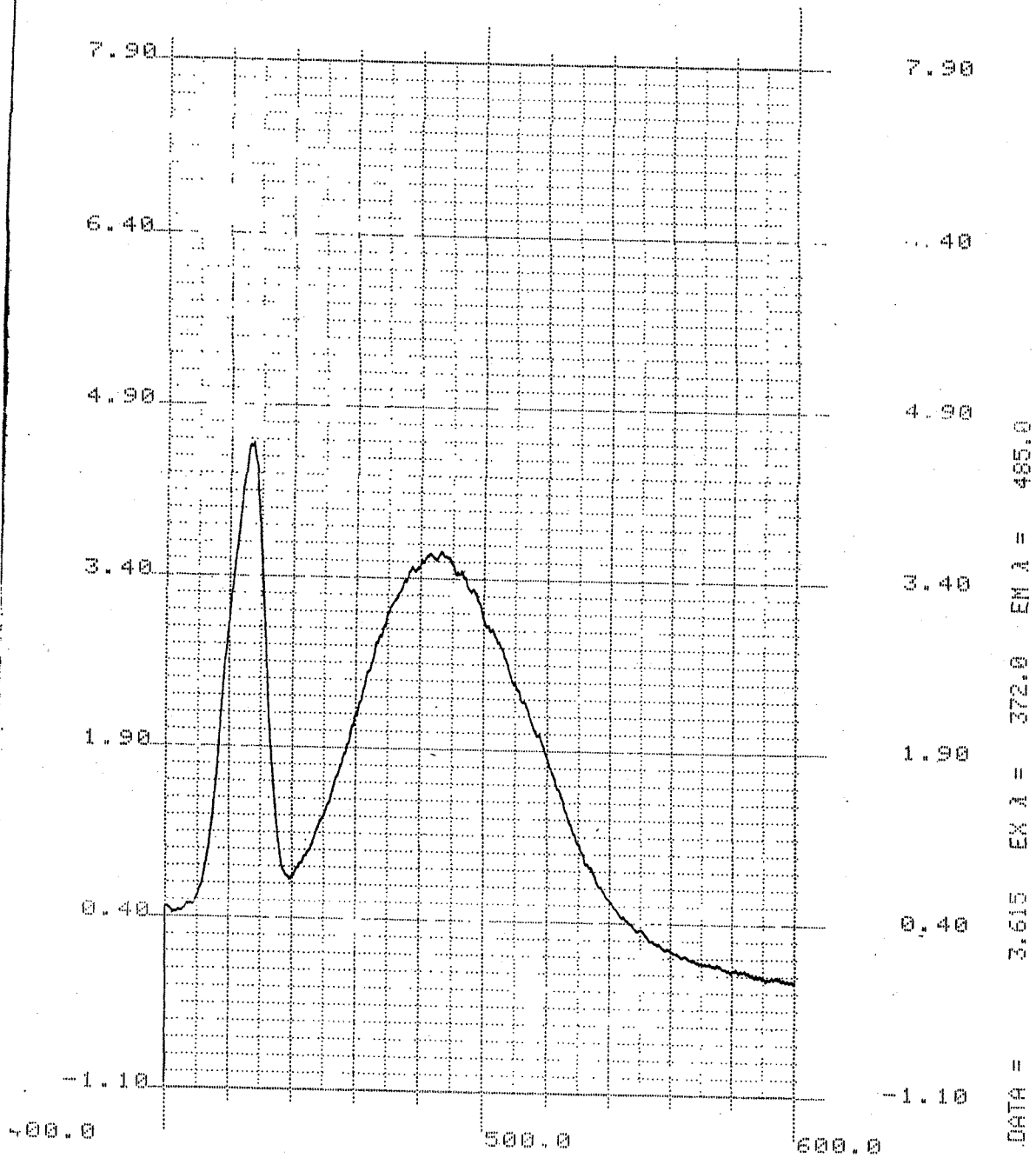
4/25/08



std 80%

⊕ SHIMADZU CORPORATION CHART 200-91527

80%



std 100%

SHIMADZU CORPORATION CHART 200-91527

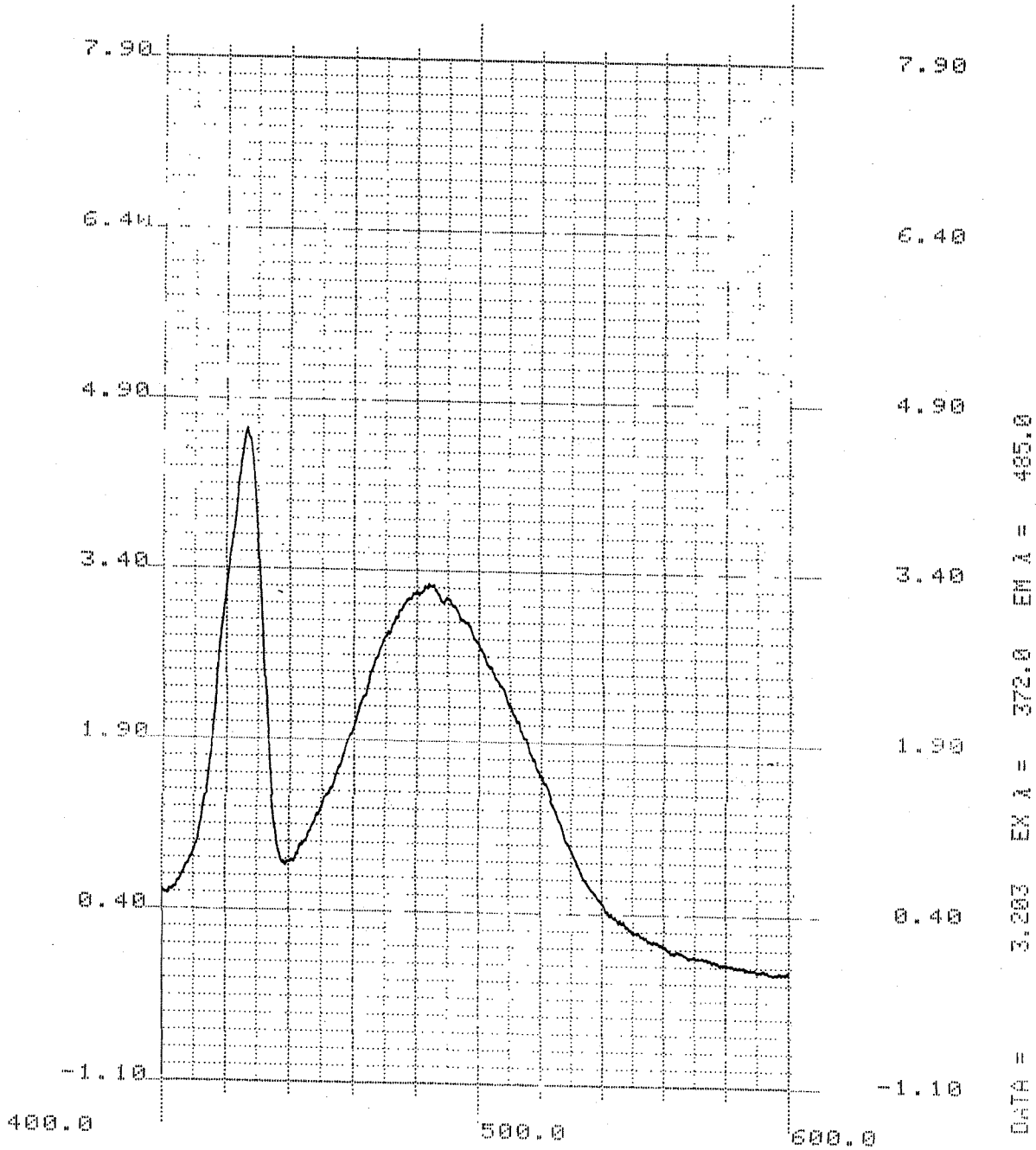
100%

Attachment B

Digoxin Tablets (0.25 mg)

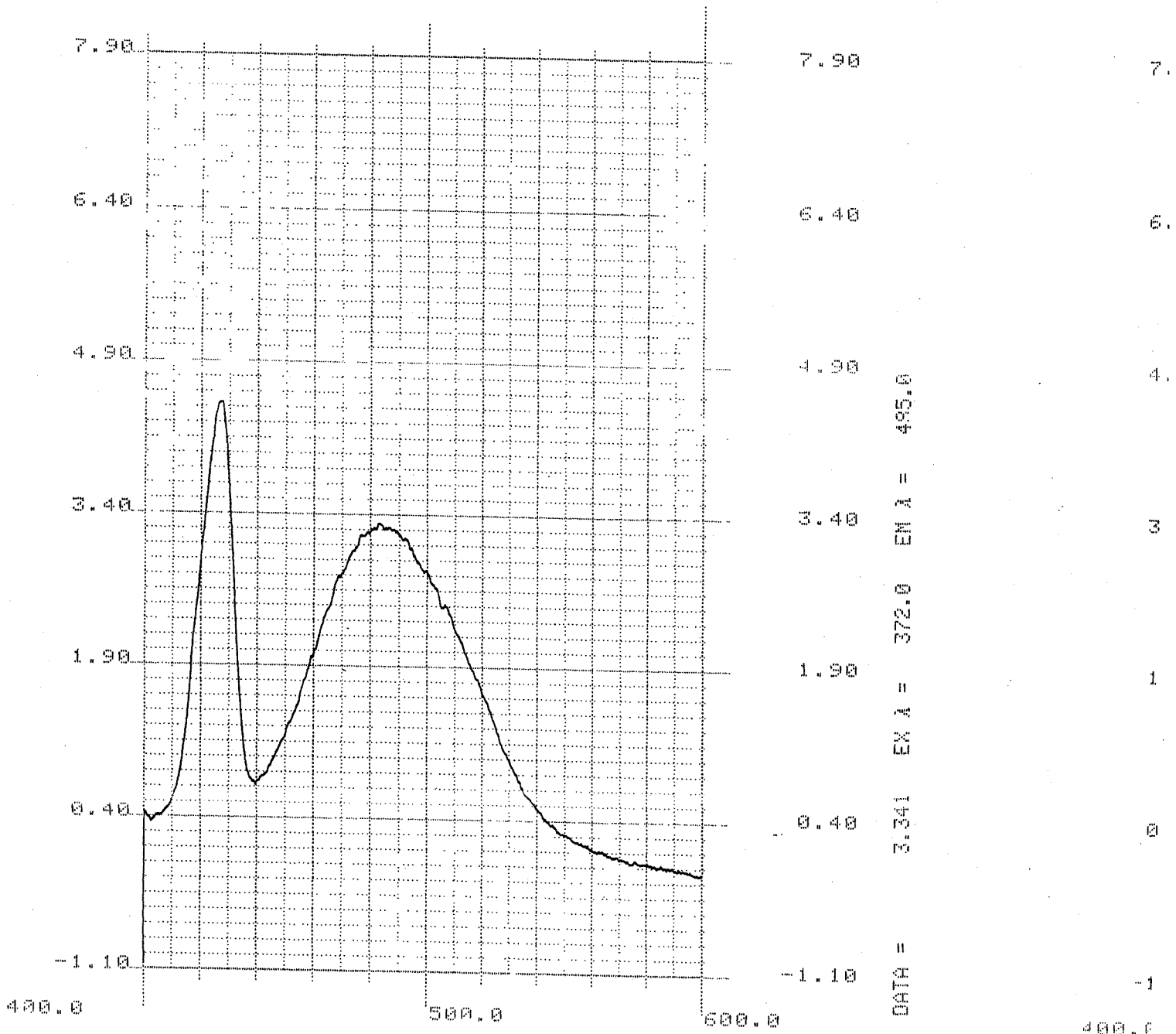
Spl.# 448892

4/25/08



DATA = 3.203 EX λ = 372.0 EM λ = 485.0

Tab 1-1



Tab 1-2

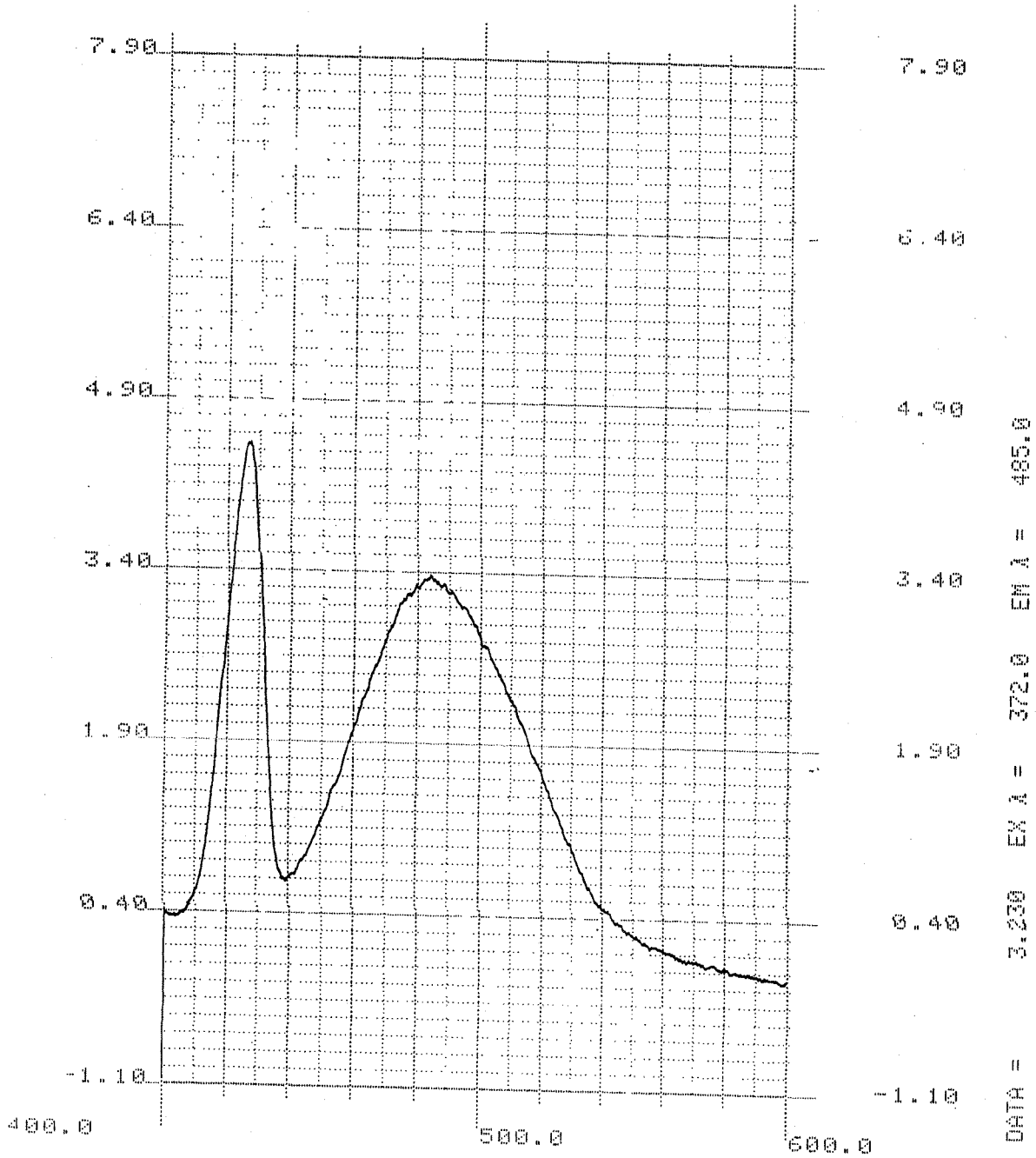
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

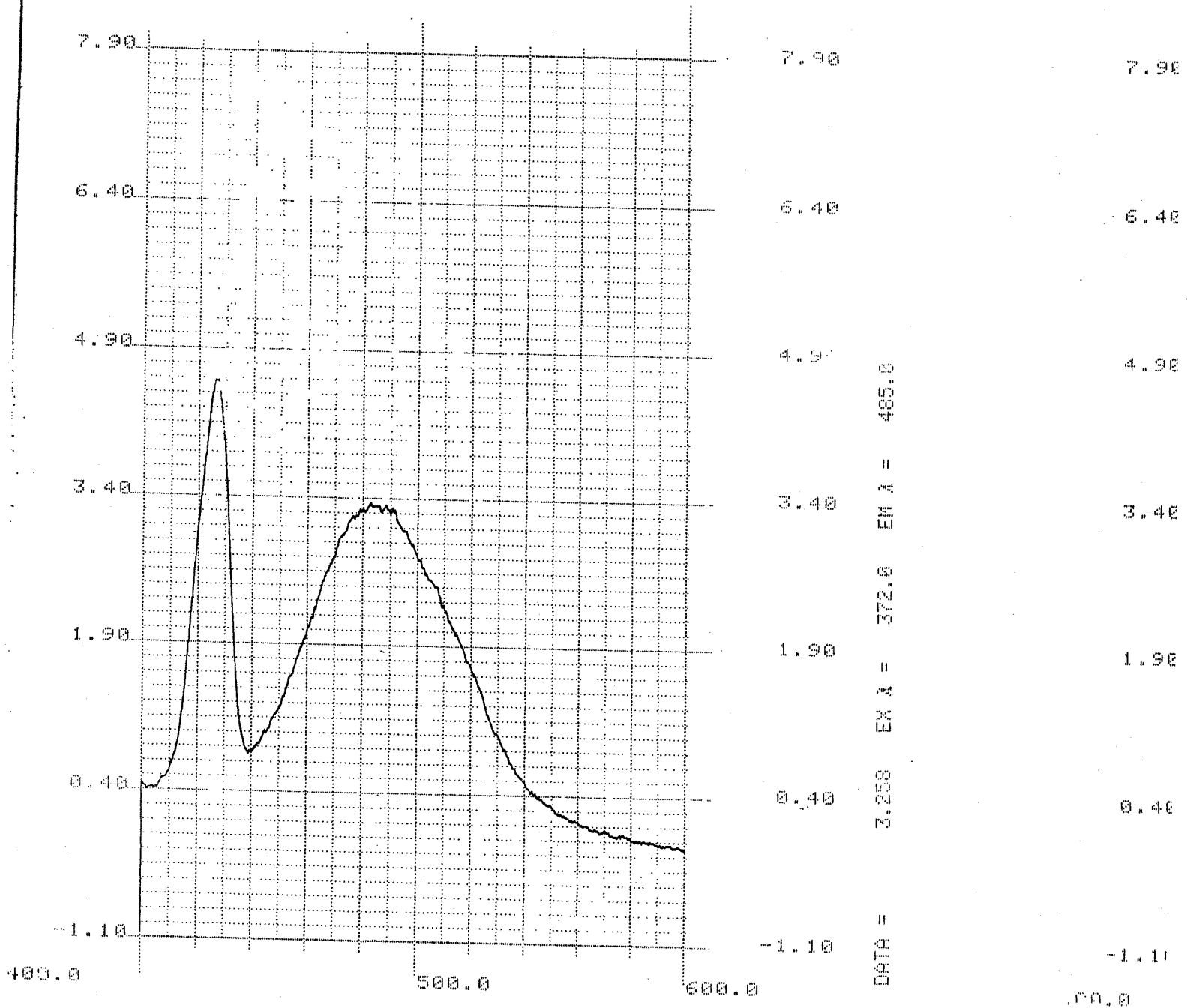
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 2-1



Tab 2-2

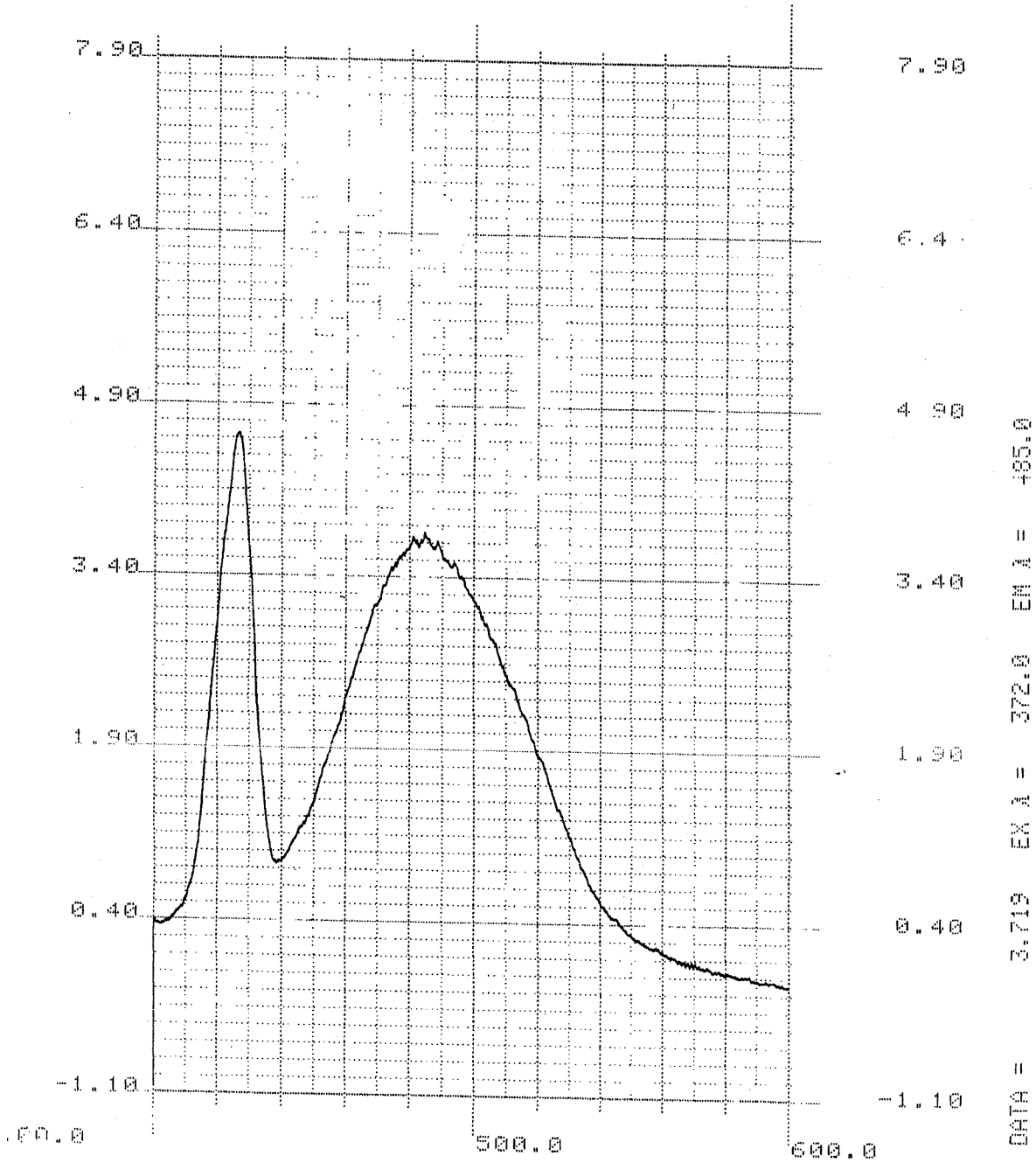
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

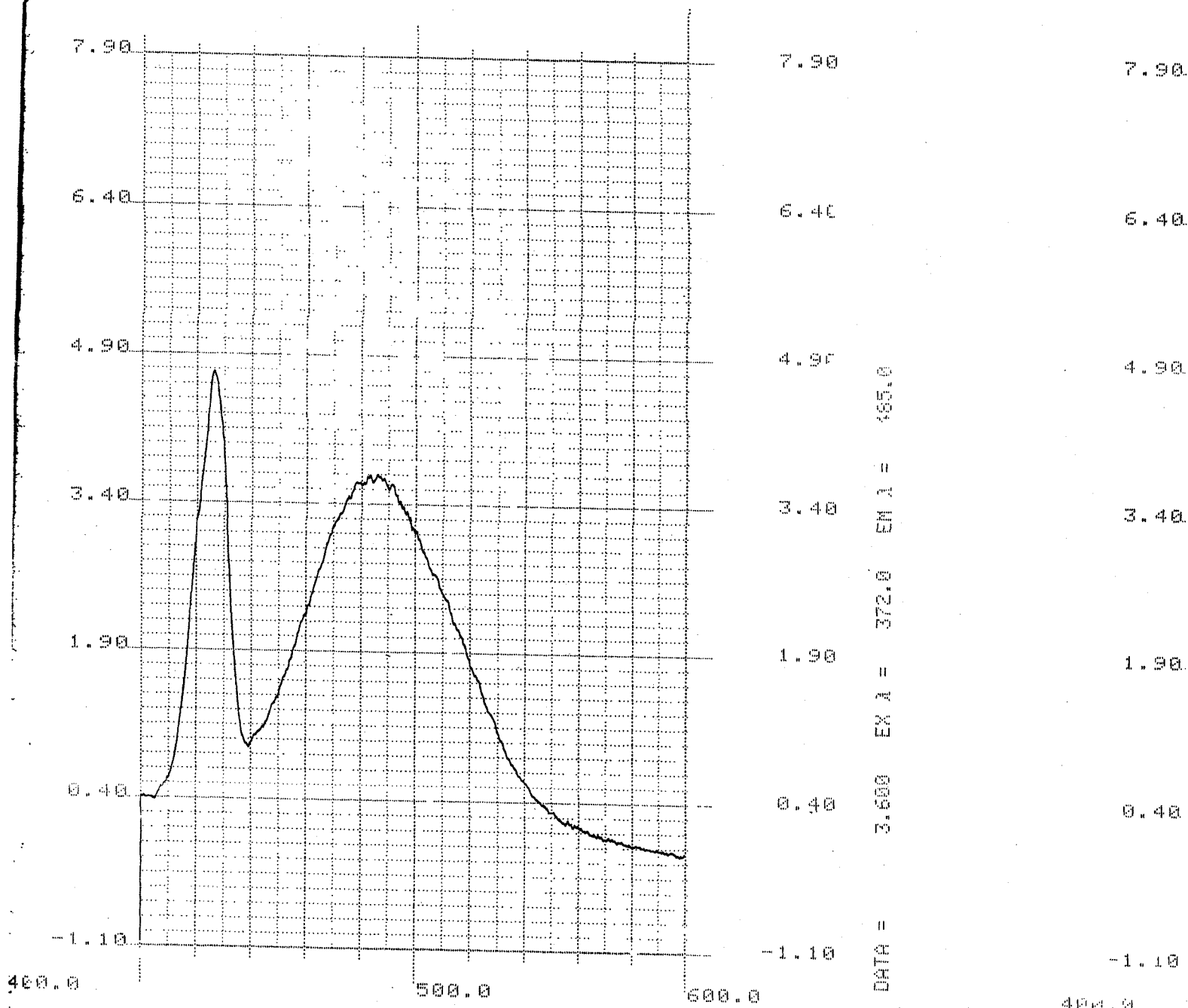
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 3-1



Tab 3-2

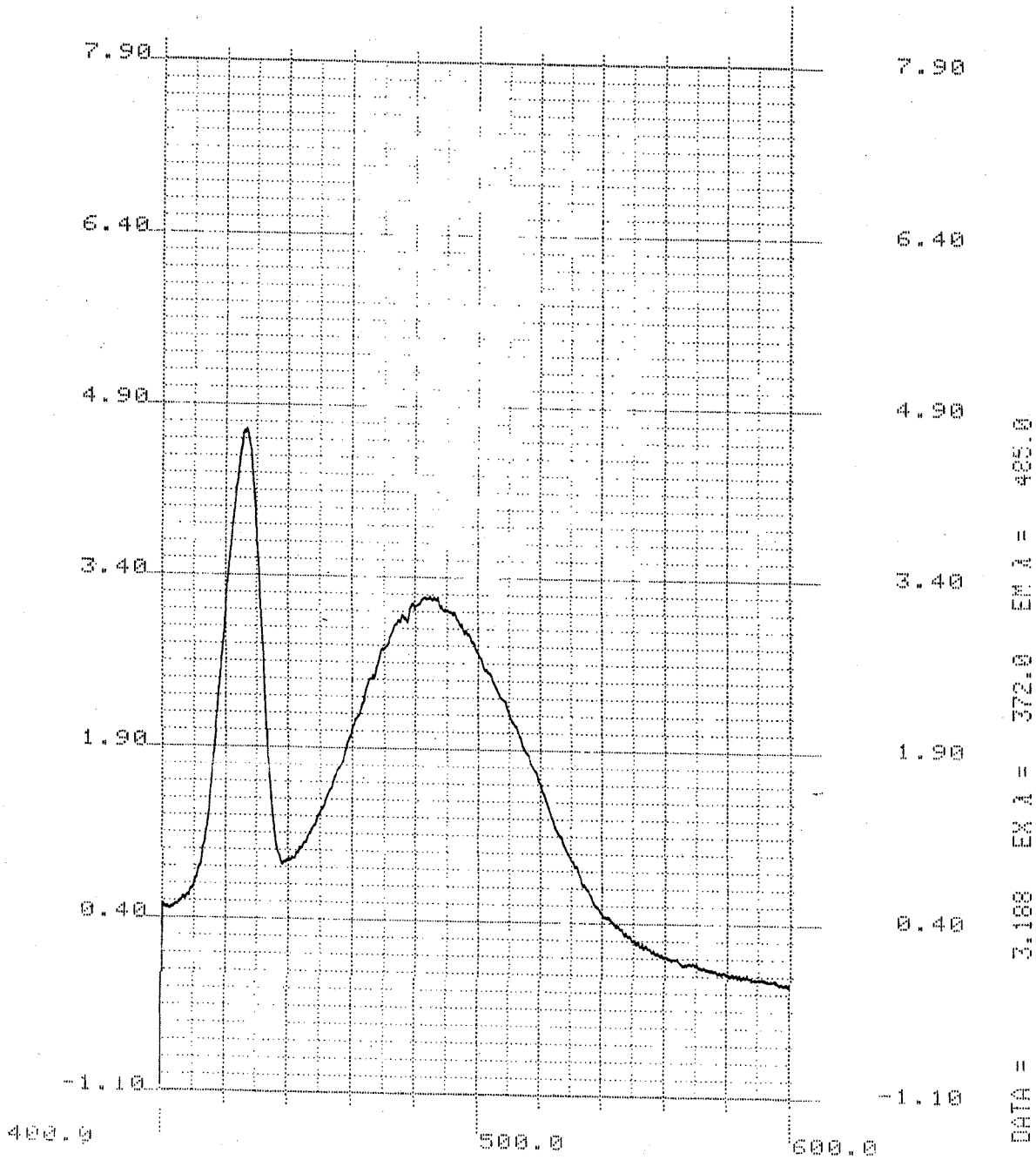
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

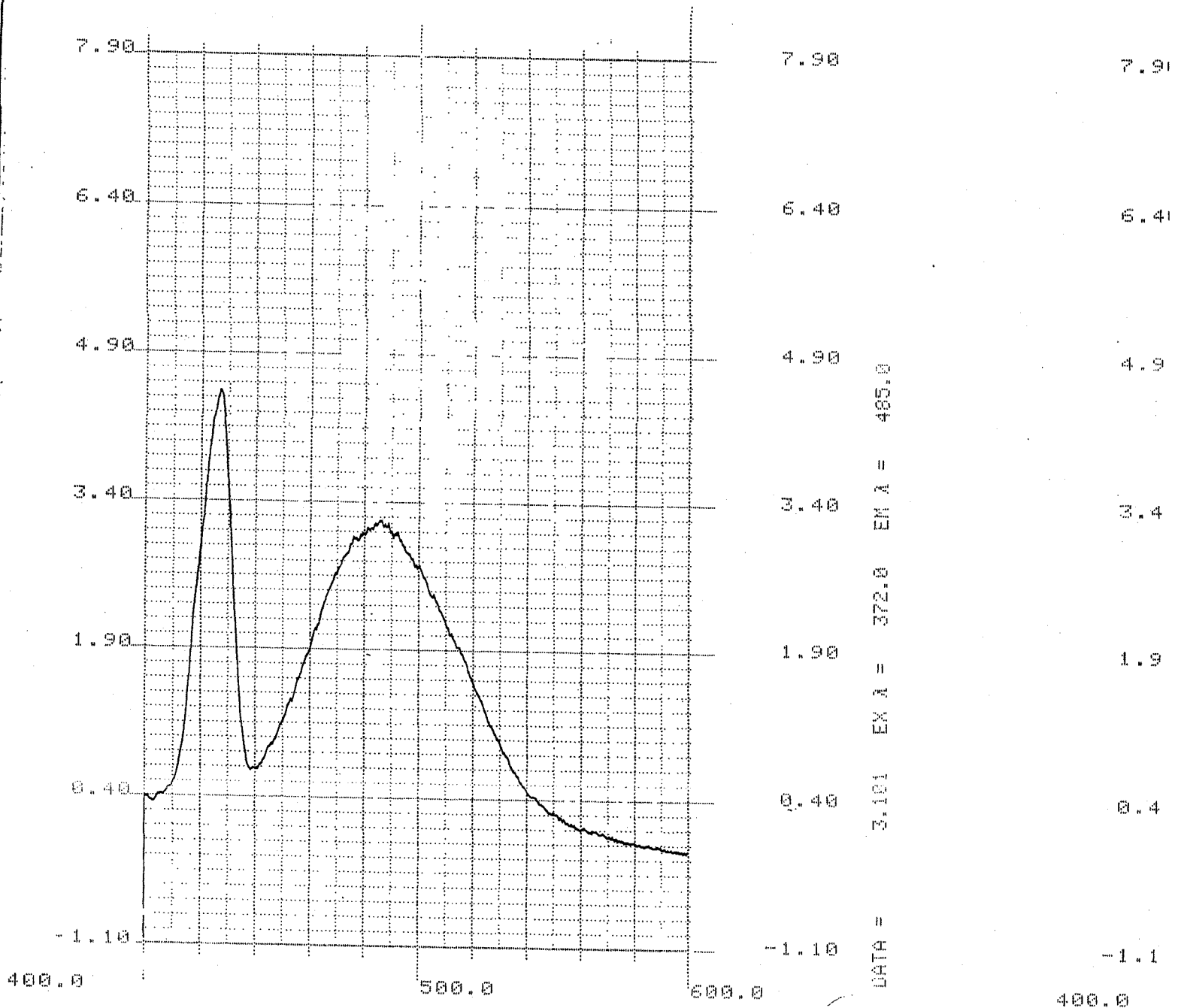
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 4-1



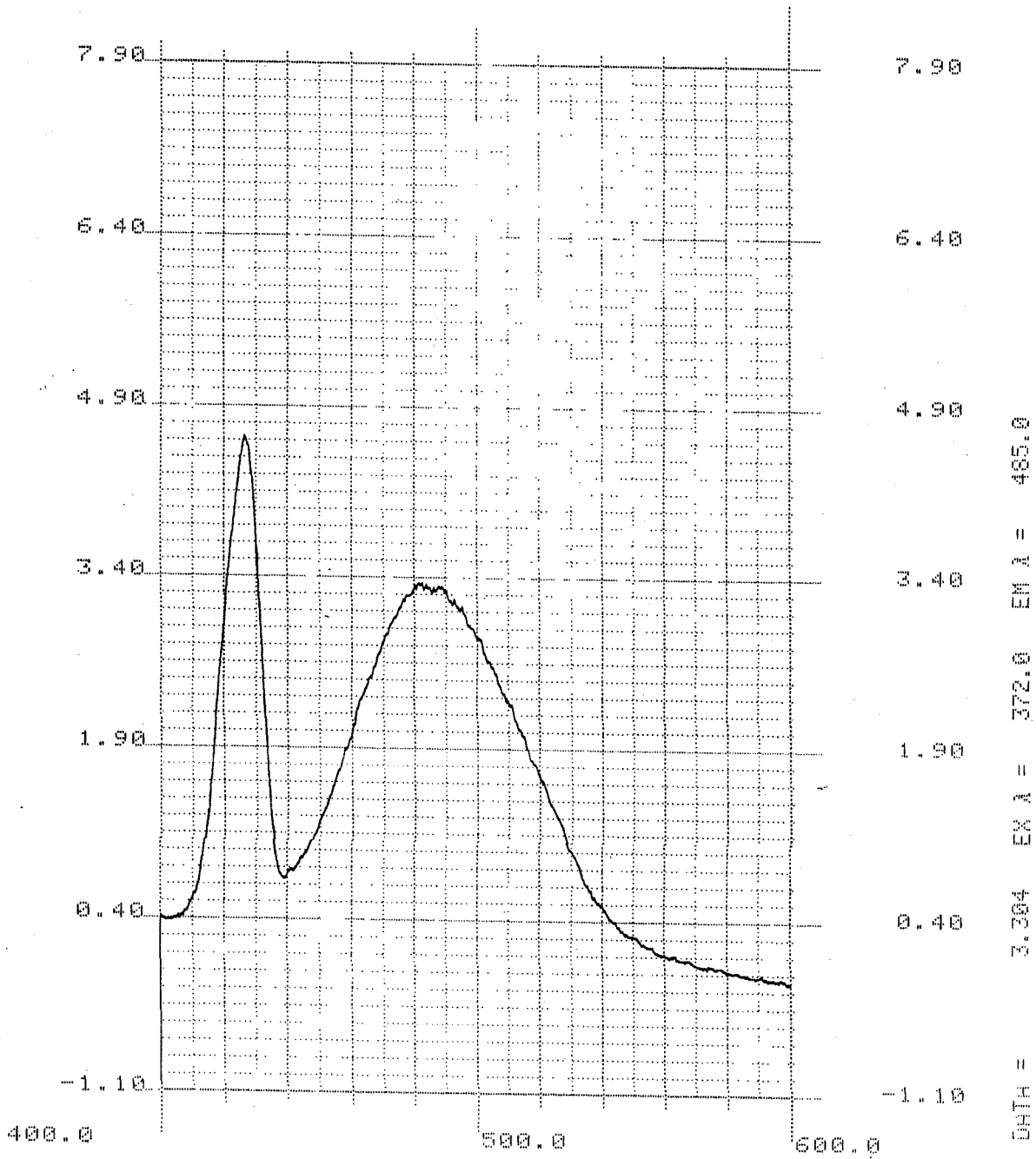
tab 4-2

Attachment B

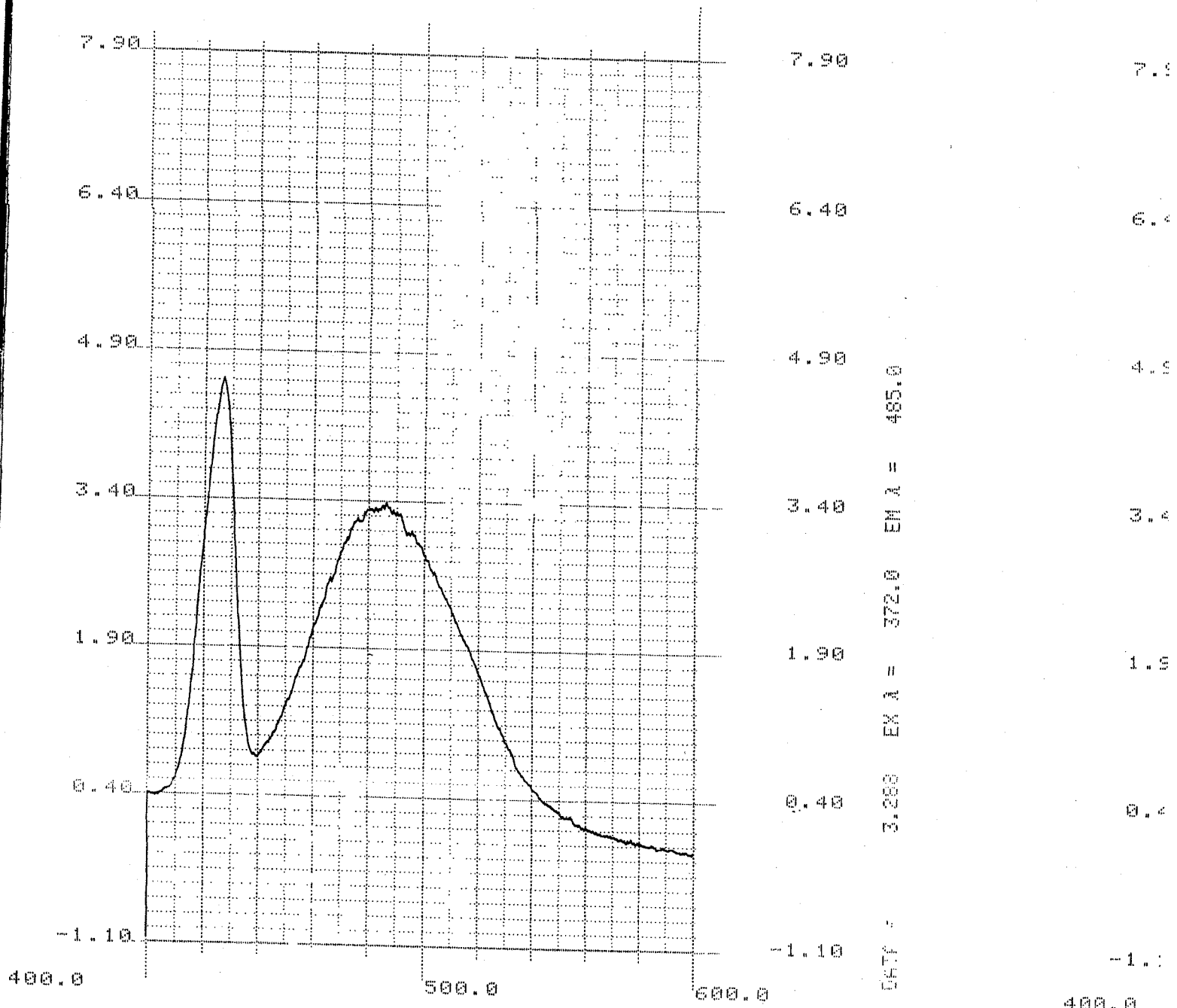
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 5-1



tab 5-2

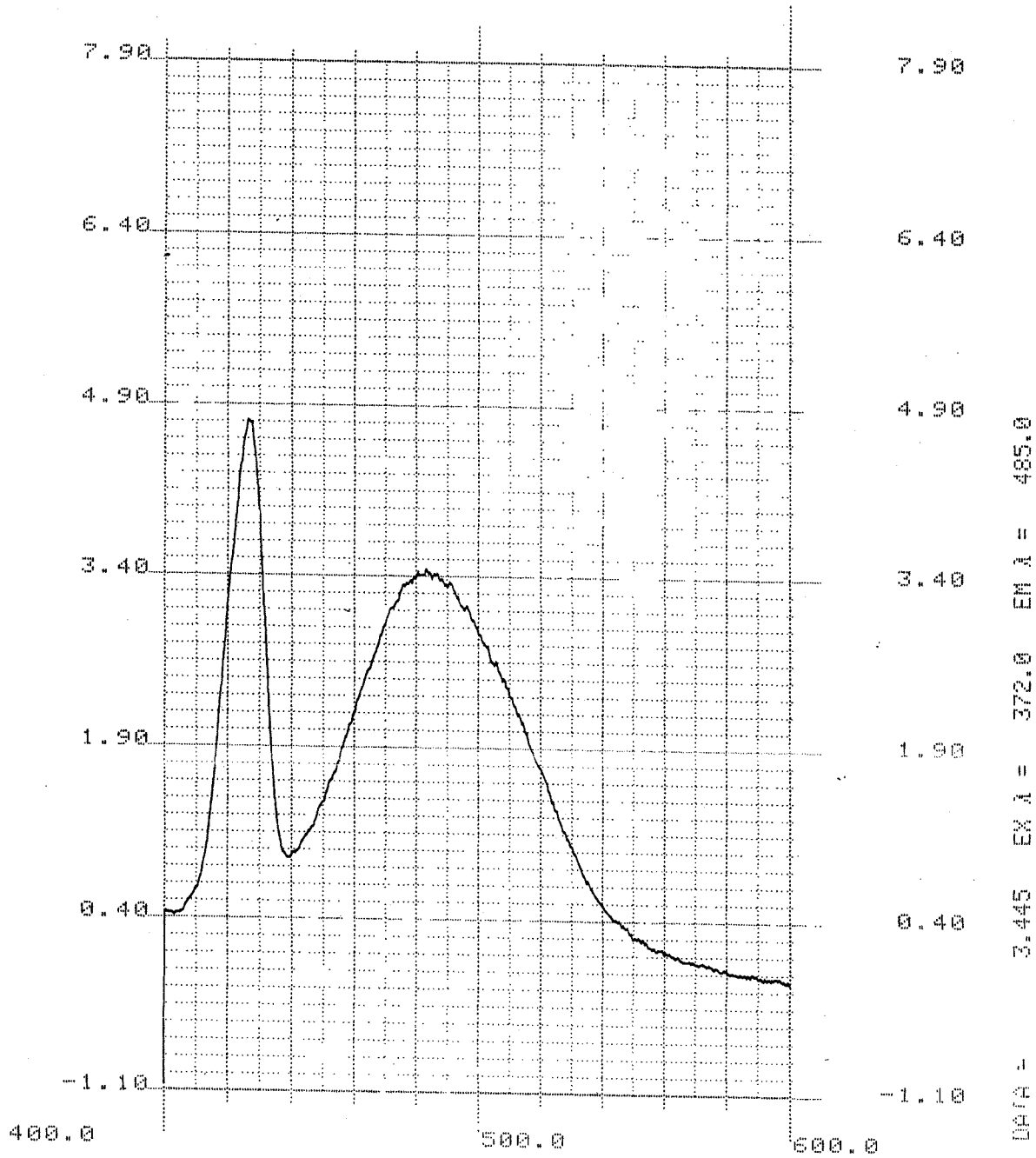
⊕ SHIMADZU CORPORATION CHART 200-91527

Attachment B

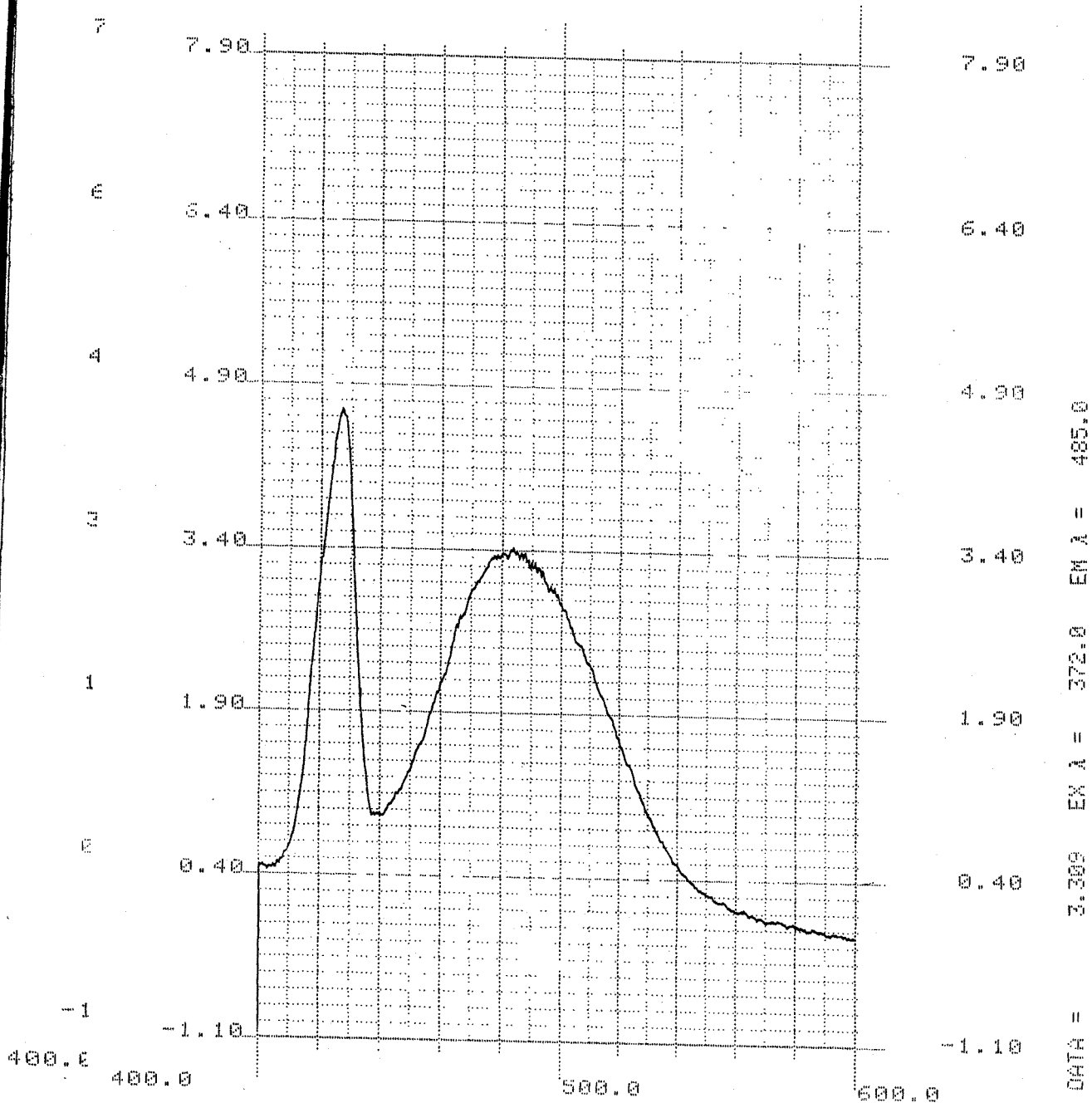
Digoxin Tablets (0.25 mg)

Spl.# 448892

4/25/08



Tab 6-1



Tab 6-2

⊕ SHIMADZU CORPORATION CHART 2

Flag
Survey Sample

Flag Remarks
FY 2008 Low Cost Generic Drug Sample Survey # 2008-800

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	0882662	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1610608	12/03/2007	63FCA06	Shipper	56008A	2
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	DET-DO	62794-146-01		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Digitek	

Product Description
100 x 0.25mg Digoxin Tablets, USP

Product Label
See continuation.

Reason for Collection
The sample was collected as per memo for the FY 2008 Low Cost Generic Drug Sample Survey # 2008-800 (CP 7356.008) and is being reported in FACTS under Assignment # 896688 and Op # 3518061.

MFG Codes
70664A1

Expiration Date
Aug 2009

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
UDL Laboratories, Inc	12720 Dairy Ashford Rd Sugar Land, TX 77478-2844 US	Shipper	1610608	
Actavis Totowa LLC	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	2244683	
Wal-Mart Pharmacy Warehouse #6028	801 Corda Blvd Crawfordsville, IN 47933-2152 US	Dealer	3004344335	
Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
(b) (4) x 100 count bottles		FDA484		

Description of Sample
The sample consists of 2 x 100 count 0.25mg Digitek (Digoxin Tablets, USP) with NDC # 62794-146-01 and assigned lot # 706641A and expiry date 8/2009.

Method of Collection
2 x 100 count bottles of 0.25mg Digitek (Digoxin Tablets, USP) lot 70664A1 were randomly selected from shelf.

How Prepared
See continuation.

Collector's Identification on Package and/or Label
"Sample # 448892 EB 12/3/07"

Collector's Identification on Seal
"448892 Ernest Bizjak 12/3/07"

Sample Delivered To
FEDEX

Date Delivered	Orig C/R & Records To
12/17/2007	DAL-DO
Lab w/Split Sample	Lab
0	NRL

Date: 01/30/2008

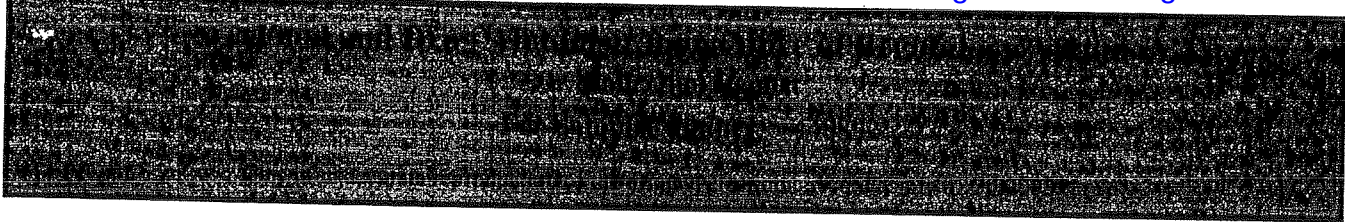
Page: 1 of 3

Document Number	Document Date	Document Type	Document Remarks
	12/03/2007	Other	FDA-482; 1 page
	12/03/2007	Other	FDA-484; 4 pages

Remarks
See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
	No Charge	No	No	Ernest Bizjak

Name of Signer	Date & Time of Signature	Meaning
Ernest Bizjak	12/14/2007 09:15 AM ET	Collector



Continuation:

Product Label

The white HDPE bottle with matching screw cap is labeled in part "NDC 62794-146-01 *** DIGITEK (digoxin tablets, USP) *** 250mcg (0.25 mg) *** 100 TABLETS *** Distributed by: BERTEK PHARMACEUTICALS INC. Sugar Land, TX 77478 *** Manufactured by: AMIDE PHARMACEUTICAL, INC. 101 East Main Street Little Falls, NJ 07424 USA *** Control No.: 70664A1 *** Exp. Date: Aug 09".

How Prepared

The 2 bottles were identified as per Collector's ID and placed into a clear Whirl-pak bag that was then officially sealed at the dealer. The sample was transported back to the DET-DO/INDY-RP where it was stored in a locked sample cabinet at ambient conditions until it was boxed and shipped to lab.

Remarks

Per assignment memo, test sample for UDU, Diss, and ID. All analytical methods are compendial.

Dena McClamroch, General Manager stated that she could not provide a dollar value for the sample. If this information is needed, contact Monty Mason, Pharmacy Director at ph#479-277-1558.